# EXHIBIT 10

**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE**

**PATENT TRIAL AND APPEAL BOARD**

VITAL CONNECT, INC.

***Petitioner***

v.

BARDY DIAGNOSTICS, INC.

***Patent Owner***

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U.S. Patent No. 11,051,743
Original Issue Date: Jul. 6, 2021
Title: ELECTROCARDIOGRAPHY PATCH

Case No. IPR2023-00381

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# PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,051,743 PURSUANT TO 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42

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## LISTING OF EXHIBITS

| Exhibit | Description |
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| Exhibit 1001 | U.S. Patent No. 11,051,743 (the "**'743 patent**") |
| Exhibit 1002 | Declaration of Dr. Dr. Joseph Akar ("**Akar**") |
| Exhibit 1003 | International Public No. WO 2010/104952 ("**Mazar**") |
| Exhibit 1004 | U.S. Patent Appl. Publ. No. 2011/0077497 ("**Oster**") |
| Exhibit 1005 | U.S. Patent No. 11,116,447 ("**Yang**") |
| Exhibit 1006 | *Curriculum Vitae* of Dr. Joseph Akar |
| Exhibit 1007 | Prosecution History of U.S. Patent No. 11,051,743 |
| Exhibit 1008 | U.S. Patent No. 5,862,803 ("**Besson**") |
| Exhibit 1009 | Gary Wolf, "*The Data-Driven Life*," New York Times Magazine, April 28, 2010 |
| Exhibit 1010 | Kashmir Hill, "*Adventures in Self-Surveillance: Fitbit, Tracking My Movement and Sleep*," Forbes, February 25, 2011 |
| Exhibit 1011 | Lori Mehen, "*Open health with the quantified self*," Opensource.com, August 25, 2011 |
| Exhibit 1012 | "*23 Personal Tools to Learn More About Yourself*," Flowingdata.com, September 18, 2008 |
| Exhibit 1013 | PCT Appl. Publ. No. WO 2008/005015 ("**Shennib**") (Exhibit 1013) |
| Exhibit 1014 | U.S. Patent No. 7,206,630 ("**Tarler**") (Exhibit 1014) |
| Exhibit 1015 | U.S. Patent No. 8,611,980 ("**Chloe**") (Exhibit 1015) |
| Exhibit 1016 | M. Puurtinen, *et al*., *Estimation of ECG Signal of closely separated bipolar electrodes using thorax models*, Proceedings of the 26th Annual International Conference of the IEEE |

| | |
|---|---|
| | EMBS pp. 801-804, San Francisco, Calif., USA, Sep. 1-5, 2004 (Exhibit 1016) |
| Exhibit 1017 | Trägårdh E, Engblom H, Pahlm O., *How many ECG leads do we need?* Cardiol Clin. 2006 Aug;24(3):317-30, vii. doi: 10.1016/j.ccl.2006.04.005. PMID: 16939826 (Exhibit 1017) |
| Exhibit 1018 | May 24, 2022, Letter from Bardy's Counsel in response to VitalConnect letter of May 2, 2022 and May 2, 2022, Letter from VitalConnect's Counsel to Bardy (Exhibit 1018) |
| Exhibit 1019 | U.S. Patent No. 9,277,864 |

## I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, Petitioner Vital Connect, Inc. ("**VitalConnect**" or "**Petitioner**") respectfully requests *inter partes* review ("**IPR**") of Claims 1-20 ("**Challenged Claims**") of U.S. Patent No. 11,051,743 (the "**'743 patent**").

The '743 patent discloses and claims a wearable wireless monitor patch for electrocardiographic and physiological monitoring. The claims are directed to the basic structure of a wireless patch (*e.g.*, electrodes, wireless transceivers, flexible circuit boards, processors, batteries) with a narrower mid-section.

But the inventors of the '743 patent did not invent the wireless electrocardiographic patch. The field of wireless medical patches was very crowded by the priority date of the '743 patent. Such devices commonly use the basic components above and wireless electrocardiographic patches with a narrow mid-section were taught by many prior art references, including the prior art relied on in this Petition. As discussed at length below, the '743 patent claims nothing that was not well-known in this highly developed field.

Petitioner requests that the PTAB institute trial and find the Challenged Claims unpatentable for the reasons set forth herein.

## II. 37 C.F.R. § 42.8(B): MANDATORY NOTICES

### A. 37 C.F.R. § 42.8(b)(1): Notice of Real-Parties-in-Interest

Petitioner certifies that the real parties-in-interest are: Vital Connect, Inc. No other parties exercised or could have exercised control over this Petition; no other parties funded or directed this Petition. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48759-60.

### B. 37 C.F.R. § 42.8(b)(2): Notice of Related Matters

To the best knowledge of Petitioner, the '743 patent has been involved in the following litigations and matters:

| Case Name | Filed |
|---|---|
| *Bardy Diagnostics, Inc. v. Vital Connect, Inc.*, Case No. 1:22-cv-00351 (D. Del.) | Mar. 18, 2022 |

### C. 37 C.F.R. § 42.8(b)(3) and (4): Notice of Counsel and Service Information

| Vital Connect, Inc. Lead Counsel | Vital Connect, Inc. Back-Up Counsel |
|---|---|
| Richard F. Martinelli<br>Reg. No. 52,003<br>Orrick, Herrington & Sutcliffe LLP<br>51 West 52nd Street<br>New York, NY 10019-6142<br>Telephone: (212) 506-3702<br>RFMPTABDocket@orrick.com | Joseph A. Chern<br>Reg. No. 63,246<br>Orrick, Herrington & Sutcliffe LLP<br>2050 Main Street, Suite 1100<br>Irvine, CA 92614-8255<br>Telephone: (949) 852-7730<br>2JAPTABDocket@orrick.com<br><br>Gerald E. Porter |

| | |
|---|---|
| | Reg. No. 74,917<br>Orrick, Herrington & Sutcliffe LLP<br>355 S. Grand Ave.<br>Los Angeles, CA 90071<br>Telephone: (213) 629-2020<br>PTABDocketG1P6@orrick.com |

Petitioner submits a Power of Attorney with this Petition. Please address all correspondence to lead counsel. Petitioner consents to service by email at the email addresses listed above.

### D. Fee for *Inter Partes* Review

The USPTO is authorized to charge the filing fee and any other fees incurred by Petitioner to the deposit account of Orrick, Herrington, & Sutcliffe LLP: 15-0665.

## III. REQUIREMENTS FOR IPR

This Petition complies with all requirements under 37 C.F.R. § 42.104 for IPR.

### A. § 42.104(a): Grounds for Standing

The '743 patent is available for IPR; Petitioner is not barred or estopped from requesting IPR*; and* this Petition for IPR is timely filed under 35 U.S.C. § 315(b).

### B. § 42.104(b): Identification of Challenge

Pursuant to 37 C.F.R. § 42.104(b), Petitioner requests that the PTAB invalidate the Challenged Claims of the '743 patent.

### 1. § 42.104(b)(1): *Challenged Claims*

Petitioner challenges Claims 1-20 of the '743 patent.

### 2. § 42.104(b)(2): *The Prior Art and Statutory Grounds*

The application for the '743 patent was filed on December 11, 2020. It claims priority to application No. 16/241,929, filed on January 7, 2019, now Pat. No. 10,888,239, which is a continuation of application No. 15/818,437, filed on Nov. 20, 2017, now Pat. No. 10,172,534, which is a continuation of application No. 15/256,266, filed on September 2, 2016, now Pat. No. 9,820,665, which is a continuation of application No. 14/082,071, filed on Nov. 15, 2013, now Pat. No. 9,433,367, which is a continuation-in-part of application No. 14/080,717, filed on Nov. 14, 2013, now Pat. No. 9,545,204, and a continuation-in-part of application No. 14/080,725, filed on November 14, 2013, now Pat. No. 9,730,593, and Provisional application No. 61/882,403, filed September 25, 2013. This Petition therefore treats **September 25, 2013**, as the priority date for the '743 patent (the "**Priority Date**").

The prior art references relied upon herein are:

| Patent/Publication | Priority Date | Publication Date | Prior Art | Ex. No. |
|---|---|---|---|---|
| International Publ. No. WO 2010/104952 ("**Mazar**") | March 10, 2009 | September 16, 2010 | 102(b) | 1003 |
| U.S. Patent Appl. Publ. No. 2011/0077497("**Oster**") | May 1, 2008 | March 31, 2011 | 102(b) | 1004 |
| U.S. Patent No. 11,116,447 ("**Yang**") | May 24, 2012 | June 30, 2016 | 102(b) | 1005 |

Below are the specific statutory grounds on which the claims are challenged:

| Ground | Reference | Claims |
|---|---|---|
| 1 | **Mazar in view of Yang** | 1–20 |
| 2 | **Oster in view of Yang** | 1–20 |

None of the references on which these grounds are based was applied by the Examiner during prosecution of the '743 patent.

### 3. *Level of Ordinary Skill in the Art*

A POSITA of the technology described in the '743 patent in 2013 would have had a bachelor's degree in cardiovascular medicine, electrophysiology, internal medicine, electrical engineering or an equivalent degree, and two to three years of clinical experience in the field of biomedical engineering. Ex. 1002, ¶ 43. Alternatively, a POSITA of the technology described in the '743 patent in 2013 would have had two or more years of medical work with knowledge of the

electronic design and operation of cardiac monitoring technologies. *Id*.

### 4. *§ 42.104(b)(5): Evidence Supporting Challenge*

The Declaration of Dr. Joseph Akar (Ex. 1002) ("**Akar**") and other supporting evidence in the Exhibit List are filed herewith. Dr. Akar's background and qualifications, and the information provided to him, are discussed in Ex. 1002 and 1006.

## IV. INSTITUTION SHOULD BE GRANTED

This Petition establishes a reasonable likelihood of success on the merits and all other requirements for an IPR.

No ground presented here was considered by the Examiner or otherwise previously considered by the Patent Office. For the reasons set forth in detail below, there is a reasonable likelihood that at least one of the Challenged Claims are unpatentable.

The parties are currently litigating the '743 patent in an action brought on March 18, 2022, by Bardy Diagnostics, Inc. ("**Bardy**" or "**Patent Owner**"). *Bardy Diagnostics, Inc. v. Vital Connect, Inc.*, Case No. 1:22-cv-00351-CJB (D. Del.) ("**Delaware Action**").

Application of the factors in *Apple Inc. v. Fintiv, Inc.*, Case No. IPR2020-00019, Paper No. 11 (Mar. 20, 2020) weigh ***against*** discretionary denial of IPR institution.

First, the district court proceeding is in its early stages. Bardy served Petitioner with its original complaint in the Delaware Action approximately nine months ago. But the case was slow to start and discovery did not open until November 2022. No claim construction positions or fact discovery has been exchanged. Is currently set for November 18, 2024, well after a final written decision in this IPR. Moreover, statistics show that the median time to trial is 36 months in Delaware. https://www.uscourts.gov/sites/default/files/fcms_na_distcomparison0630.2022_0.pdf at p. 3.

Second, Petitioner has been diligent in expeditiously preparing and filing this Petition. A *Markman* hearing has been scheduled in the Delaware action for September 2023, and it is unlikely the Court will have issued its claim construction order by the institution deadline.

Third, the grounds asserted in this Petition are exceptionally strong. The Petition shows that the '743 patent claims nothing more than conventional wireless patch features, and there are multiple grounds of invalidity for each Challenged Claim. This factor alone is sufficient to avoid any discretionary denial. *See*, Director Vidal June 21, 2022 Memorandum re *Fintiv.*

Accordingly, IPR should be instituted.

## V. THERE EXISTS A REASONABLE LIKELIHOOD THAT THE CHALLENGED CLAIMS ARE UNPATENTABLE

### A. Technology Background

The '743 patent is entitled "Electrocardiography Patch" and discloses and claims a wearable patch for wireless, electrocardiography monitoring. As explained by Dr. Akar's, the field of electrocardiography monitoring was well-established and built upon the understanding of well-known physiological monitoring techniques by the '743 patent's priority date. Ex. 1002, ¶¶ 23-32, 47-52, 60-64, 69-104. It was a crowded art that employed well understood concepts that were predictable, and routinely mixed and matched to achieve a POSITA's design goals. *Id*.

#### 1. '743 Patent Background

The '743 patent assumes a POSITA understands basic biomedical principles. For example, an electrocardiogram (ECG) measures and records electrical signals from the heart to diagnose heart problems and other potential health concerns. Ex. 1001, 1:29-31, 43-44; Ex. 1002, ¶¶ 24-32, 49-50. An ECG reader includes electrodes placed on the patient's skin to sense cardiac electrical activity. Ex. 1001, 1:34-42; Ex. 1002, ¶¶ 25, 30-32.

A typical ECG is recorded over 12 seconds, which could be insufficient to completely diagnose many cardiac disorders. Ex. 1001,1:44-59; Ex. 1002, ¶ 51.

Diagnostic efficacy can be improved with long-term extended ECG monitoring. Ex. 1001, 1:44-49, 60-61; Ex. 1002, ¶ 51. The patent describes prior art Holter monitors, which allow for extended monitoring of 24-48 hours or more. Ex. 1001, 2:36-57; Ex. 1002, ¶ 51. The patent, however, criticizes these devices as cumbersome, expensive, and only able to provide limited recording. *Id.*

The '743 patent describes the prior art "ZIO XT Patch" and the "ZIO Event Card," which can meet the recognized "gold standard" of a 30-day observation period. Ex. 1001, 2:58-3:18, 1:65-2:2; Ex. 1002, ¶ 52. The '743 patent explains that the ZIO XT Patch "combines both electronic recordation components, including battery, and physical electrode into a unitary assembly that adheres to the patient's skin." Ex. 1001, 2:67-3:8; Ex. 1002, ¶ 52. The '743 patent criticizes the ZIO XT Patch's battery capacity and lack of waterproof electronics. Ex. 1001, 3:8-15; Ex. 1002, ¶ 52. The '743 patent also recognizes that many prior art consumer devices enable users to record physiological information and that the concept is so well-known that it had been established as the "quantified self" movement. Ex. 1001, 3:19-35; Ex. 1002, ¶ 52.

**2. Problem Addressed by the '743 Patent**

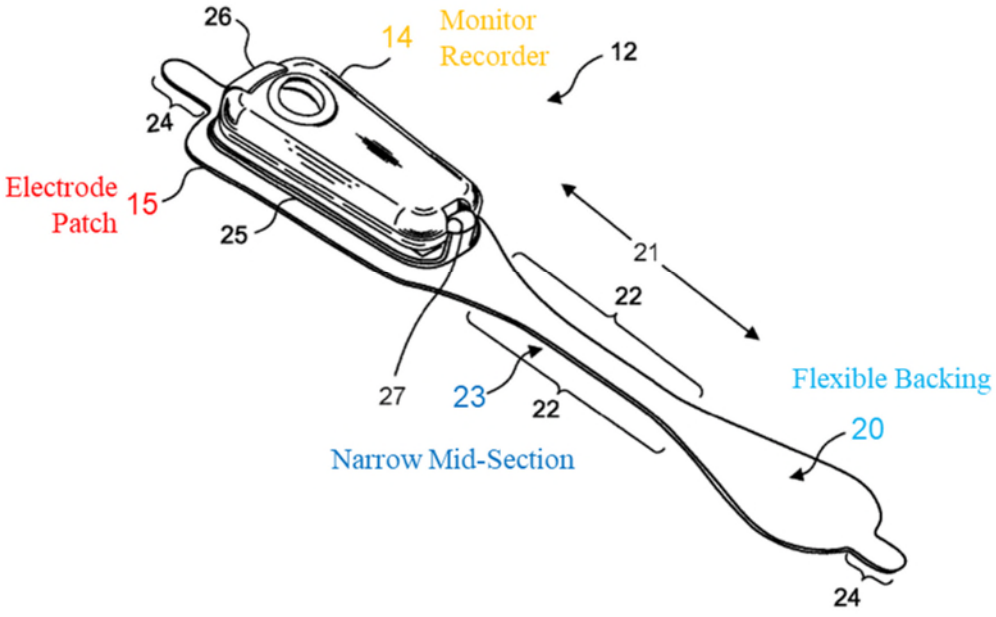
The '743 patent asserts "a need remains for an extended wear continuously recording ECG monitor practically capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably." Ex.

1001, 3:36-39; Ex. 1002, ¶ 53. As well as a need "to integrate wider-ranging physiological and 'life tracking'-type data into long-term ECG and physiological data monitoring." Ex. 1001, 3:40-42; Ex. 1002, ¶ 53.

### B. The Alleged Invention

The '743 patent describes an ECG monitoring patch comprising two primary components: a flexible extended wear electrode patch and a removable reusable monitor recorder. Ex. 1001, 3:45-49; Ex. 1002, ¶ 54. Fig. 4 (*below*) shows the ECG sensor monitor 12 including a monitor recorder 14 and an electrode patch 15. Ex. 1001, Fig. 4; 5:44-61; Ex. 1002, ¶ 54.

**Fig. 4.**




The monitor 12 comprises a narrow mid-section 23 purportedly to benefit the long-term extended wear. Ex. 1001, 3:51-56; Ex. 1002, ¶ 55. The patient can

place an electrode patch anywhere within the general region of the sternum, which puts the ECG electrodes in a location better adapted to sensing signals from the heart. Ex. 1001, 6:1-15; Ex. 1002, ¶ 55.

The patch 15 has a flexible backing 20 shaped as an elongated strip 21 and a removable battery compartment 36. Ex. 1001, 9:55-10:10; Ex. 1002, ¶ 56.

To address the insufficient memory issues of prior art systems, the '743 patent describes compressing the monitored data prior to storage in flash memory 62 while space remains available. Ex. 1001, 13:60-14:10; Ex. 1002, ¶ 57. The monitored data is wirelessly offloaded to a remote server. Ex. 1001, 15:2-29; Ex. 1002, ¶ 57.

### C. Prosecution History

The '743 patent stems from Application No. 17/119,945, filed on December 11, 2020, and claims priority to a September 25, 2013, Provisional Application (No. 61/882,403). Facing no substantive prior art rejections, the '743 patent was allowed after a single-office action, which merely rejected the pending claims based on double patenting over its parent 10,888,239. Ex. 1007, pp. 175-180 (January 25, 2021, Office Action). The Examiner explained that compared to the '239 patent, the claims were not patentably distinct because "[t]he skilled artisan would recognize narrowing a mid-section between the two ends of a backing obviously reduces weight by eliminating unnecessary material." *Id.* at 178. The

Examiner concluded that it was similarly "obvious to provide an accelerometer to measure movement and a hydrocolloid adhesive to attach the device to a patient." *Id*. Bardy did not rebut these assertions and submitted a terminal disclaimer to overcome the rejection. *Id.*, pp. 104-105 (Response to First Office Action). A Notice of Allowance followed.. *Id.* p. 15 (ANotice of Allowance). The '743 patent issued on July 6, 2021. *Id.* p. 4 (Issue Notification).

### D. Claim Constructions

IPR claims are construed "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 42 C.F.R. §42.100(b).

Petitioner one proposed claim construction to address an argument raised by Bardy. Petitioner does not believe that any other constructions are needed to address the validity issues raised in this petition. *See*, *e.g.*, *Netflix, Inc. v. Uniloc 2017 LLC*, Case No. IPR2020-00041, Paper No. 10 at 15 (Mar. 25, 2020). Petitioner reserves the right to respond to any constructions offered by Bardy.

#### 1. "*a battery on one of the ends of the backing*" (Claim 11)

The term "a battery on one of the ends of the backing" of claim 11 should be construed according to its plain and ordinary meaning. Ex. 1002, ¶ 106. In the parties' litigation, Bardy has argued that the term should be construed to exclude intervening components between the battery and the backing, which is incorrect. If

the term is construed, it means "a battery on one end of the backing or the other end of the backing" and it ***does not*** require the battery to be affixed to the backing with no intervening components. Ex. 1002, ¶¶ 107-108.

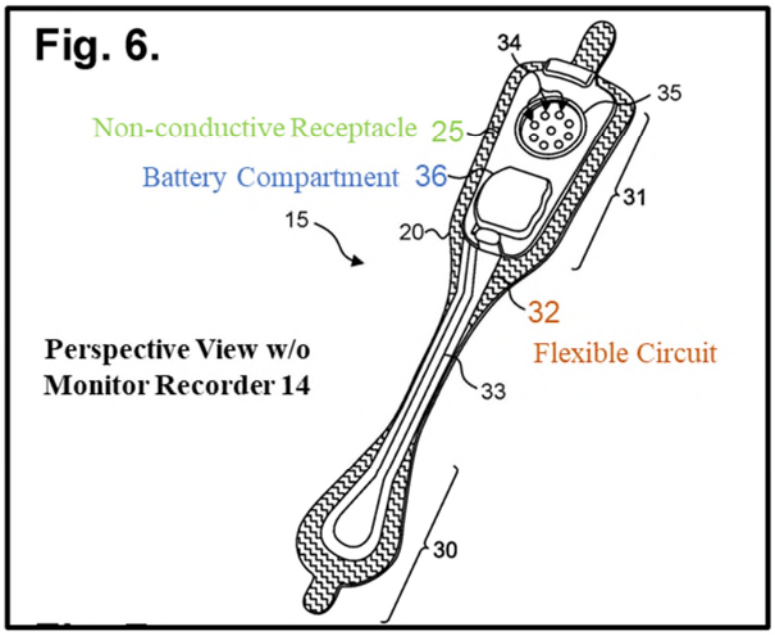
In response to the Complaint, Petitioner's counsel wrote a letter to Bardy on May 2, 2022, *inter alia*, detailing that the subject patent is invalid as anticipated or obvious, for example, in view of the Mazar reference cited herein. *See* Ex. 1018, 5-10 Bardy's counsel responded on May 24, 2022, arguing that the claims distinguish from the prior art Mazar reference because the Mazar publication describes the batteries (150) as 'separated from' the backing (111) and 'positioned over the flex printed circuit board and electrical components.'" Ex. 1018, 1-4.

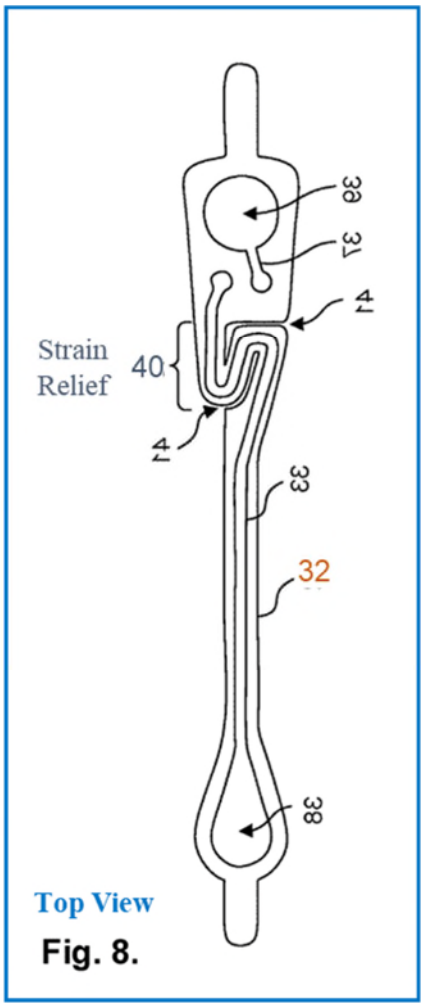
Contrary to Bardy's arguments, the term is directed to the general positioning of the battery on the body of the patch. Ex. 1002, ¶ 109. The claim phrase does not say "a battery on the backing;" it says "a battery on ***one of the ends*** of the backing." *Id*. This shows that "on" is governing the positioning of the battery relative to the ends of the backing, *i.e.*, the battery is placed on one end or the other. *Id*. This is consistent with the overall context of the claim, in which "the ends" are claimed as "a backing comprising an elongated strip with a midsection connecting two ***ends of the backing***." *Id*. This language orients "the ends" relative to the elongate shape of the patch. *Id*. And the battery limitation places the battery on one end of the patch or the other. *Id*.

Bardy's assertion that "on" requires direct contact between the backing and the battery is inconsistent with the intrinsic and extrinsic evidence. Ex. 1002, ¶ 110.

The plain and ordinary meaning of "on" does not require direct contact for one object to be "on" another. Ex. 1002, ¶ 111. A coat can be hanging "on" a coat rack even if it is hanging directly "on" a hanger, which is in turn hanging "on" the rack. *Id*. Similarly, a book is "on" a table even it if sits on top of a stack of books, rather than directly contacting the surface of the table. *Id*.

The intrinsic record supports Petitioner's construction because it does not disclose a battery in direct contact with a backing. Ex. 1002, ¶ 112. The '743 patent describes its battery compartment 36 as formed on the bottom surface of the non-conductive receptacle 25. Ex. 1001, 10:5-6, Figs. 6, 8 (reproduced below); Ex. 1002, ¶ 112. This non-conductive receptacle is mounted to the flexible circuit 32, which is, in turn, mounted on the backing. Ex. 1001, 10:20-29; Ex. 1002, ¶ 112.




The '743 patent confirms that "[a] strain relief 40 is defined in the flexible circuit 32 at a location that is partially underneath the battery compartment 36 when the flexible circuit 32 is affixed to the flexible backing 20." Ex. 1001, 10:55-58; Ex. 1002, ¶ 113. The '743 patent's own embodiment describes intervening components between the backing and the battery, specifically, the battery compartment 36 and the flexible circuit 32. Ex. 1002, ¶ 113. Notably, there are no embodiments in the '743 patent where the battery is directly on the backing with no intervening components. Ex. 1002, ¶ 113; *see Oatey Co. v. IPS Corp.*, 514 F.3d

1271, 1276-77 (Fed. Cir. 2008) ( "[w]e normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification,") ; *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (a claim interpretation that excludes a preferred embodiment is "rarely, if ever, correct"). Thus, the specification does not support Bardy's narrow construction and mandates Petitioner's proposed construction. Ex. 1002, ¶¶ 113-14.

### E. The '743 Patent Claim Elements

Claim 1 of the '743 patent is set forth below with the elements labeled for reference:

| Element Designation | Element |
|---|---|
| [**1-PRE**] | An electrocardiography patch, comprising: |
| [**1-A**] | a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing; |
| [**1-B**] | an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals; |
| [**1-C**] | a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes; and |
| **[1-D]** | a wireless transceiver to communicate at least a portion of the electrocardiographic signals. |

Claim 11 of the '743 patent is set forth below with the elements labeled for reference:

| Element Designation | Element |
|---|---|
| [**11-PRE**] | An electrocardiography patch, comprising: |
| [**11-A**] | a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing; |
| [**11-B**] | an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals; |
| [**1-C**] | a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes; |
| **[11-D]** | a wireless transceiver to communicate at least a portion of the electrocardiographic signals; |
| **[11-E]** | a battery on one of the ends of the backing; |
| **[11-F]** | a processor powered by the battery; and |
| **[11-G]** | memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals. |

## VI. THE PRIOR ART

### A. Mazar

*Mazar* discloses a patient health monitoring patch, and describes the collection and transmission of data from the device. Ex. 1003, ¶¶ [0006]-[0007], [0051]. Like the '743 patent, *Mazar* criticizes prior art monitoring devices to be bulky and uncomfortable to use. *Id.*, ¶¶ [0002]-[0005]. *Mazar* recognized that, in order to ensure consistent, comfortable health monitoring of patients, it was well-known to: (1) use a comfortable, adherent patch device; (2) that was capable of wirelessly outputting patient data. *Id.*, ¶¶ [0002]-[0005]. *Mazar's* patch

monitoring device provides solutions to these issues.

Figs. 1E, 1F1, and 1J1 (*below*) are used to explain the operation of *Mazar*'s system:

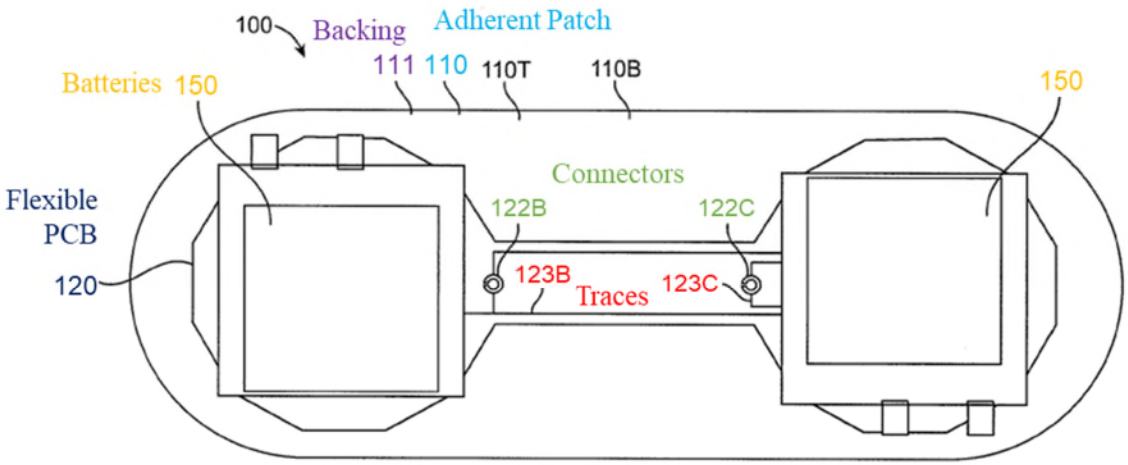



FIG. 1E

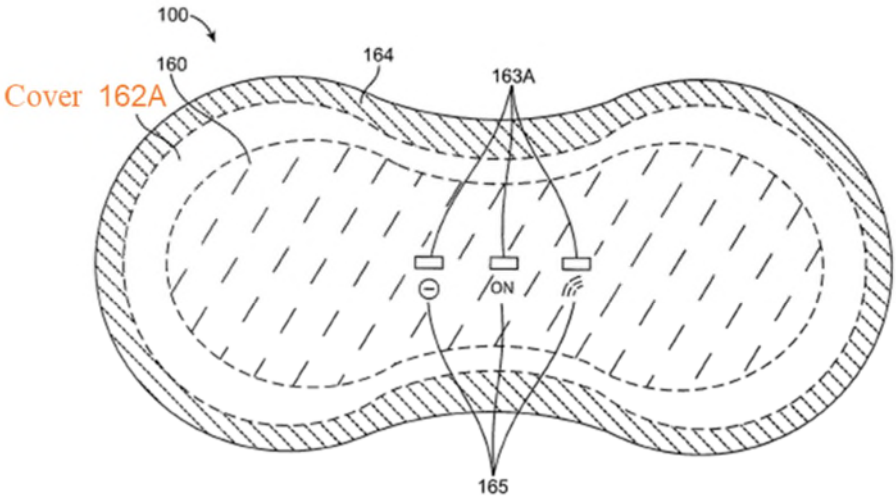



FIG. 1F1

(Top View)

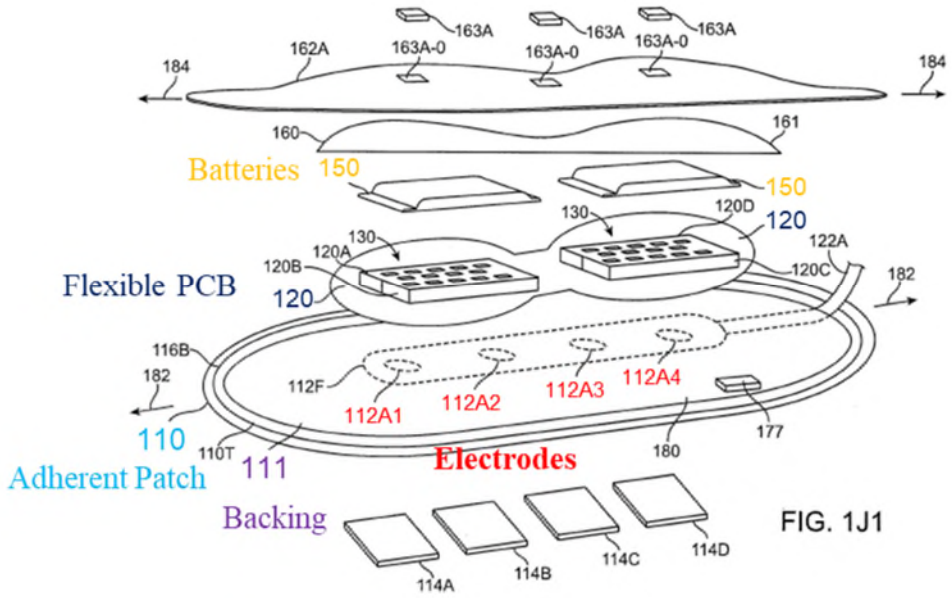



FIG. 1J1

The adherent device (100) preforms physiological monitoring, including the electrocardiogram (ECG), of a patent. *Id.* at ¶¶ [0002], [0098]. The electrodes (112A1, 112A2, 112A3, and 112A4) are affixed to the patch (110) to capture electrocardiographic signals. *Id.* at ¶ [0098].

*Mazar's* patch (110) has a backing (111) that comprises an hourglass shape that is narrower in the middle. *Id.* at ¶¶ [0093], [0127]; *see also* Fig. 1F1.

*Mazar's* electronics components (130) and communications circuitry (132) facilitate wireless communication of physiological data, including ECG data. *Id.* at ¶ [0104]-[0105]. *Mazar* discloses circuit traces to electrically couple the electrocardiographic electrodes. *Id.* at ¶ [0100]; *see also* Fig. 1D.

*Mazar* further teaches that inclusion of a battery, processor, and memory for the storing of physiological signals. *Id.* at ¶¶ [0033], [0048], [0094]-[0095],

[0104], [0167].

### B. Oster

*Oster* discloses a biomedical sensor system on a patch including electrodes for ECG monitoring and diagnostics. Ex. 1004, ¶ [0021]. The biomedical sensor system provides remote monitoring by transmitting data from the sensor to a receiver. *Id.*, ¶ [0022].

Figs. 1 and 2 illustrate the biomedical sensor system 100. *Id.*, Figs. 1, 2.

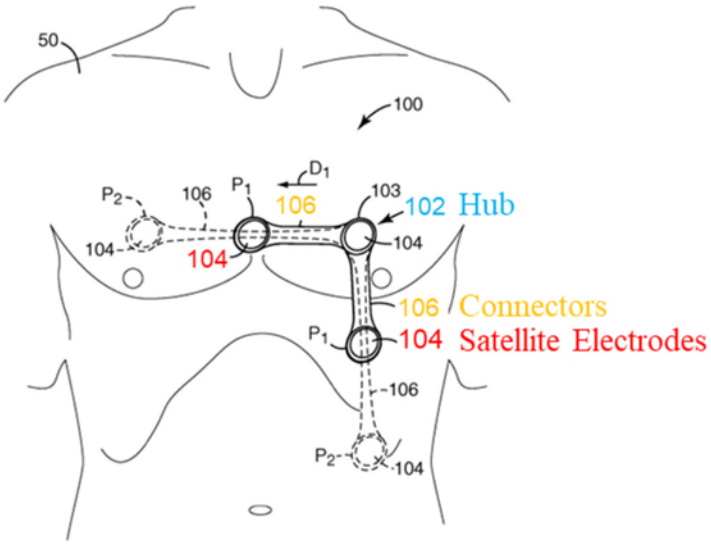



*Fig. 1*

Fig. 1 (above) illustrates system 100 in a first, unstretched, state, and a second, stretched state. *Id.*, ¶ [0030]. Fig. 1 shows the sensor system 100 including a hub 102, two satellite electrodes 104, and two connectors 106 positioned to couple each satellite electrode 104 to the hub 102. *Id.*, ¶ [0031]. The connectors 106 provide a pathway to send signals between the electrodes 104 . *Id.*

The hub 102 provides a single connection site for the biomedical sensor system 100. *Id*., ¶ [0032]. The hub 102 is disclosed as wirelessly communicating with downstream computing, processing, displaying and/or archiving equipment. *Id*. The hub 102 includes memory 116 to store information received from the electrodes 104 prior to transmitting (*e.g.*, via wireless transmitter 108) to downstream computers. *Id*., ¶ [0040].

Each electrode 104 has a surface electrode (*e.g.*, disposable), a suction electrode, a floating metal body-surface electrode, a dry electrode, or a combination thereof. *Id*., ¶ [0043]. *Oster* discloses that a variety of lead configurations are well known for capturing an ECG (*e.g.*, 3-lead, 5-lead, 12-lead). *Id*., ¶ [0029].

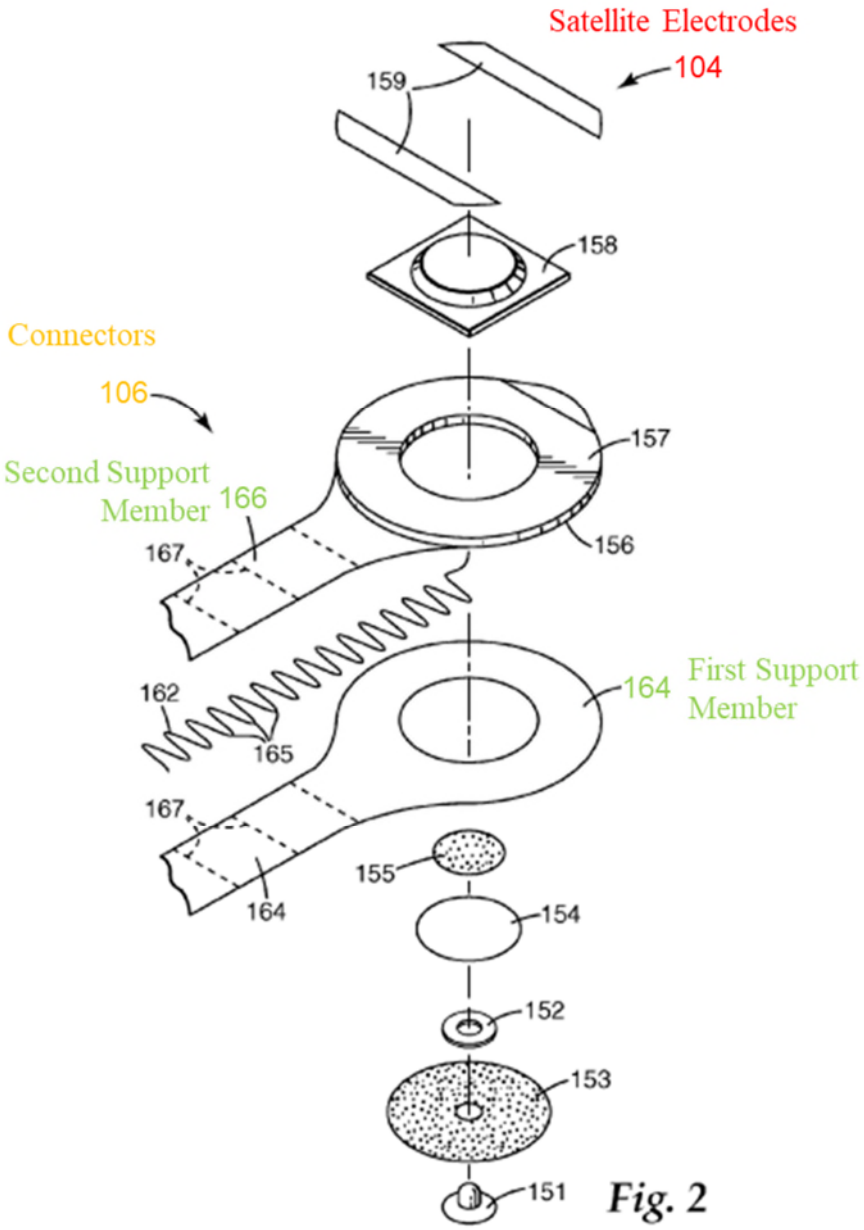



*Fig. 2*

An adhesive couples the electrodes 104 (and/or the hub 102) to the subject's skin. *Id.*, ¶ [0062]. The adhesive is coupled (*e.g.*, directly or indirectly) to at least a portion of the connector 106, such as one or more of the support members 164, 166, which in turn functions as the "backing" to the stretch release adhesive. *Id.*, ¶ [0062]. As a result, the connector 106 (*e.g.*, one or more of the support members

164, 166) includes one or more stretchable layers that can be stretched to a point that causes debonding of the adhesive. *Id*., ¶ [0062].

The biomedical sensor system 100 is size-configurable and conformable to the subject 50, at least partially because of the variable-length connectors 106. *Id*., ¶ [0051]. The connector 106 is partially formed of a viscoelastic material, such that by applying force to the connector 106 substantially along the length of the connector 106 (*e.g.*, direction $D_1$), the connector 106 can be elongated. *Id*., ¶ [0051]. The connector 106 is illustrated in Fig. 2 as comprising a wire conductor 162 positioned between a first support member 164, and a second support member 166 to provide an electrical communication pathway between the hub 102 and the electrode 104. *Id*., ¶ [0057].

### C. Yang

*Yang* is a prior art patent of Petitioner that discloses a modular wearable sensor patch attached to a user for health monitoring. Ex. 1005, Abstract, 2:24-50. Claiming priority over a year before the '743 priority date, *Yang* discloses recognized that conventional wireless sensor devices for health monitoring are subject to repeated use and high wear and tear and must be replaced regularly for routine health monitoring. *Id*., 1:18-31; *see also* Ex. 1019. *Yang* proposed a wireless sensor device with a reusable module and a disposable module that each decouple from each other for ease of replacement. Ex. 1018, 2:35-40.

Fig. 1 illustrates the modular wearable sensor 100 that looks like a band-aid and adheres to the user's body. *Id.*, 2:50-57; Fig. 1 (shown below).

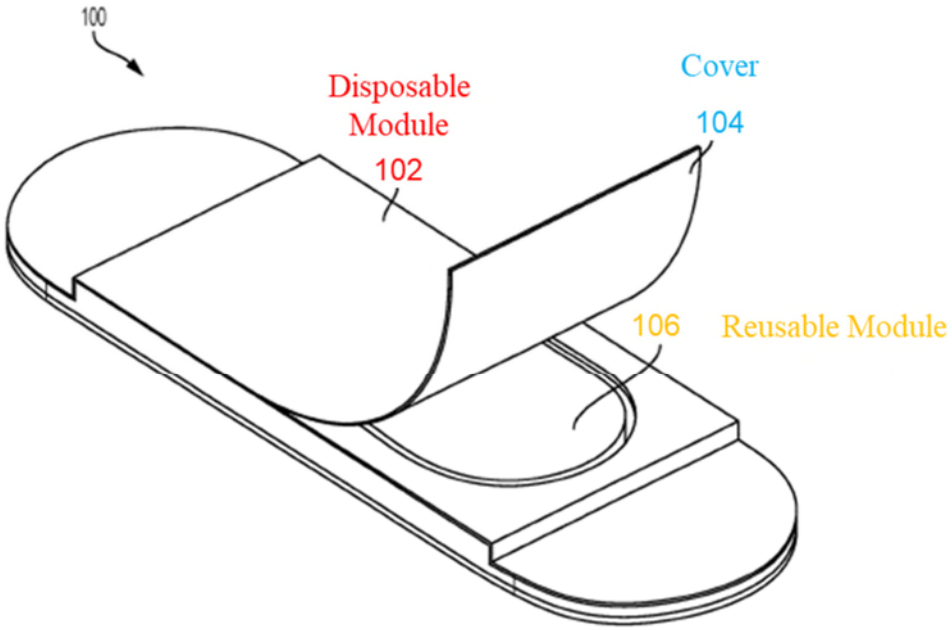



FIG. 1

Sensor 100 includes a disposable module 102, a flexible cover 104 coupled to the disposable module 102, and a reusable module 106 coupled to the disposable module 102. *Id.*, 2:57-3:2.

The disposable module 102 is soft, flexible, and stretchable to provide wear comfort when attached to the body, and can include the cover 104, foam layers, at least one power source (*e.g.*, a coin battery or a button battery), a flexible printed circuit board (PCB) including electrical components such as sensors, electrode contacts to couple electrodes, and adhesive layers. *Id.*, 3:16-28, 41-45.

The reusable module 106 houses other reusable electronics including an antenna, a microcontroller, a sensor, and a wireless transceiver. *Id.*, 3:29-39.

Fig. 3 illustrates an exploded view of a disposable module 300.

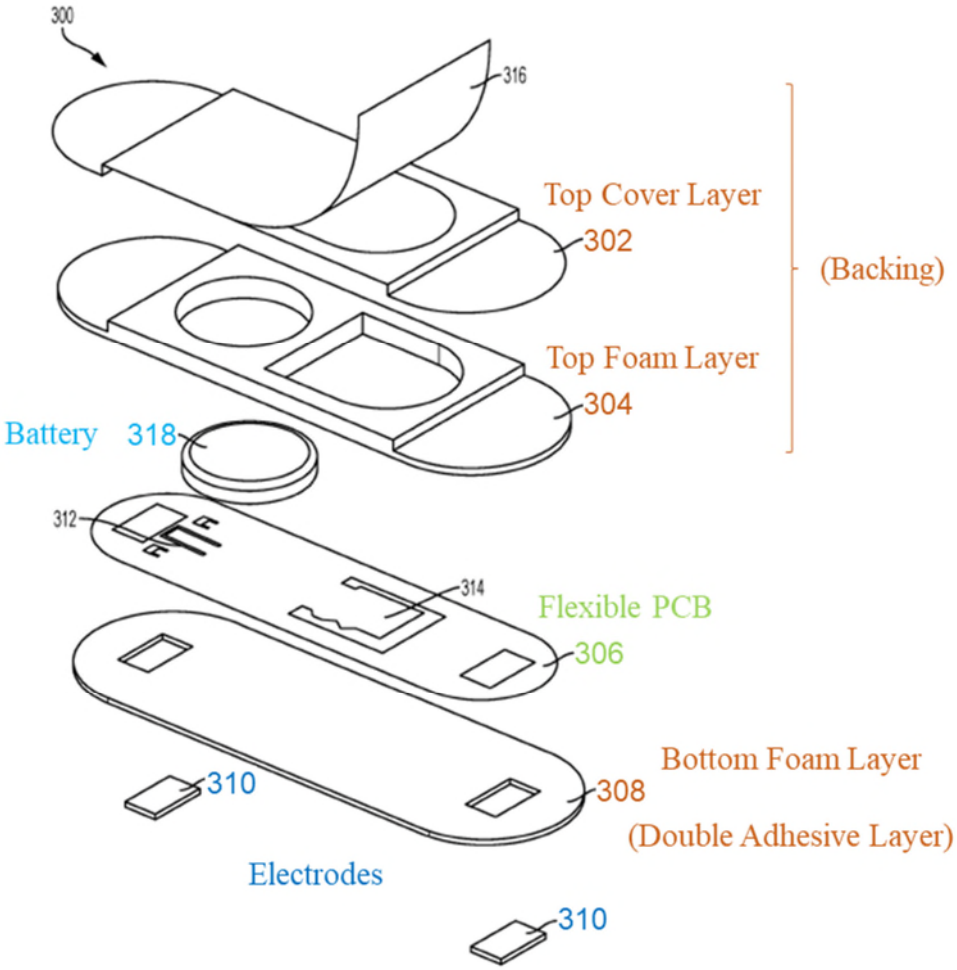



FIG. 3

The disposable module 300 includes a top cover layer 302, a top foam layer 304 coupled to the top cover layer 302, a flexible PCB 306 coupled to the top foam layer 304, a bottom foam layer 308 coupled to the flexible PCB 306, and at least two electrodes 310 coupled to the flexible PCB 306. *Id.*, 3:63-4:2. The flexible

PCB 306 enables the disposable module 300 to conform and adhere to a user's movements. *Id*., 3:2-4.

The bottom foam layer 310 can be a double-adhesive layer to adhere to the flexible PCB 306 and to a user at the same time. *Id*., 3:9-11.

### D. Motivation to Combine Mazar and Yang

A POSITA would have found it obvious to combine the systems and methods of *Mazar* and *Yang*. Ex. 1002, ¶¶ 91-97.

A POSITA would have been aware of a variety of known wireless sensor devices for remote health monitoring, like each of the biomedical sensor systems disclosed in *Mazar* and *Yang*. *Id*. A POSITA would have combined the various features of *Mazar* and *Yang* to provide additional cost-effective features to provide a comfortable, adherent patch device, as highlighted separately by each reference. *Id*.

Each of *Mazar* and *Yang* address problems of conventional at-home patient monitoring patches that each references with an eye towards improving, among other things, comfort and/or durability. Ex. 1002, ¶ 93; Ex. 1003, ¶ [0007]; Ex. 1005, 1:18-32. Each reference proceeds to then detail the benefits of its cost-effective adhesive patch, particularly in the context of health monitoring and, even more specifically, for measuring electrocardiography. Ex. 1002, ¶ 93; Ex. 1003, ¶ [0026]; Ex. 1005, 1:22-25.

In fact, a POSITA would recognize that *Yang* discloses a simple structure that is more cost-effective and easier to create than the multi-component system of *Mazar*, for example. Ex. 1002, ¶ 94. Therefore, just as the Examiner asserted during prosecution of the '743 patent, a skilled artisan would recognize that minimizing additional components of *Mazar*, such as taught by *Yang*, can reduce weight by eliminating unnecessary material. *Id*. Additionally, a skilled artisan would recognize that a reduction of the backing's size (*i.e.*, footprint) is beneficial for the patient's comfort and to reduce patient skin irritation. *Id*.

Furthermore, *Yang* discloses that a POSITA would be aware of the variety of device types that can be used for the reusable module 106, containing the processor and other electronics, and the disposable module 102, which includes, for example, known batteries and/or adhesives. Ex. 1002, ¶ 95; Ex. 1005, 3:40-45. *Mazar* confirms these components are well-known and, like *Yang*, details the advantages of the particular arrangement of these components. Ex. 1002, ¶ 95; Ex. 1003, *e.g.*, ¶ [0125].

Given the fact that these references are both directed to solving the same problem in the same application, a POSITA would recognize that the two systems can be used together to create a compatible, integrated solution to that common problem identified by each reference without requiring undue experimentation. Ex. 1002, ¶ 96. Further motivations to combine the references are described below

with respect to the specific grounds.

### E. Motivation to Combine Oster and Yang

A POSITA would have found it obvious to combine the systems and methods of *Oster* and *Yang*. Ex. 1002, ¶¶ 98-104.

A POSITA would have been aware of a variety of known wireless sensor devices for remote health monitoring, like each of the biomedical sensor systems disclosed in *Oster* and *Yang*. *Id*. A POSITA would have combined the various features of *Oster* and *Yang* to provide additional cost-effective features to provide a comfortable, adherent patch device, as highlighted separately by each reference. *Id*.

Each of *Oster* and *Yang* recognizes the importance of comfort and durability for a patch intended for regular use. Ex. 1002, ¶ 100; Ex. 1004, ¶ [0023]; Ex. 1005, 1:18-32. Each reference details the goals of creating a cost-effective adhesive patch, particularly in the context of health monitoring and, even more specifically, for measuring electrocardiography. Ex. 1002, ¶ 100; Ex. 1004, ¶¶ [0023]-[0025]; Ex. 1005, 1:22-25.

In fact, a POSITA would recognize that *Yang* discloses a simple structure with the goal of creating a cost-effective biomedical sensor. Ex. 1002, ¶ 101; Ex. 1005, 1:22-25. Similarly, *Oster* expressly teaches reducing the waste created in manufacturing and constructions of diagnostic patches to enhance safety and

subject comfort. Ex. 1002, ¶ 101; Ex. 1004, ¶¶ [0023]-[0024]. Therefore, a skilled artisan would recognize that minimizing additional components of a biomedical sensor, such as taught by both references, can enhance safety, comfort, and ease of use. Ex. 1002, ¶ 101.

Furthermore, *Yang* discloses that a POSITA would be aware of the variety of device types that can be used for the reusable module 106, containing the processor and other electronics, and the disposable module 102, which includes, for example, known sensors for measuring a variety of health related values including ECG and respiratory rates. Ex. 1002, ¶ 102; Ex. 1005, 4:9-15. *Oster* confirms these components are well-known and, like *Yang*, details the variety of lead configurations that can be used, for example, for an ECG, such as the arrangement disclosed in the '743 patent. Ex. 1002, ¶ 102; Ex. 1004, *e.g.*, ¶ [0029].

Given the fact that these references are both directed to solving the same problem in the same application, a POSITA would recognize that the two systems can be used together to create a compatible, integrated solution to that common problem identified by each reference without requiring undue experimentation. Ex. 1002, ¶ 103. Further motivations to combine the references are described below with respect to the specific grounds.

## VII. CLAIMS 1-20 OF THE '743 PATENT ARE UNPATENTABLE OVER THE PRIOR ART

### A. GROUND 1: Mazar In View of Yang Renders Claims 1-20 Obvious

A POSITA would have found it obvious and predictable to combine features of *Mazar's* adherent patch device with the teachings of *Yang* to achieve a patch with the particular advantages of components as taught in each of the references, as explained in Section VI.D above and further below. Ex. 1002 ¶¶ 91-97.

#### 1. Independent Claim 1

*Mazar* and *Yang* disclose the method of Claim 1 as described below with reference to the Claim element designations. *See* Section V.E.

##### a) Element [1-PRE]

*Mazar* and *Yang* are in the same field and both disclose "[a]n electrocardiography patch" as claimed by this element. *Mazar* discloses an **adherent patch device** capable of physiological monitoring patients, including measuring the electrocardiogram (ECG), for extended periods. Ex. 1003, ¶¶ [0002], [0098]; *see also* Fig. 1F1; Ex. 1002 ¶ 121. Similarly, *Yang* discloses a modular wearable sensor device in a "patch" form that is attached to the user for health monitoring, such as for ECG measurements. Ex. 1005, 2:24-50; Ex. 1002 ¶ 122.

A POSITA would understand that both *Mazar* and *Yang* disclose this

element. Ex. 1002, ¶¶ 121-122.

**b) Element [1-A]**

*Mazar* and *Yang* disclose "a backing comprising an elongated strip with a mid-section connecting two ends of the backing." Ex. 1002 ¶¶ 124, 126. And *Mazar* further discloses an elongated patch having a "mid-section [that] is narrower than the two ends of the backing." Ex. 1002 ¶ 124. *Mazar* teaches that its adherent device 100 includes an adherent patch 110, which includes a backing material, or **backing 111**, such as fabric configured to provide properties of patch 110. Ex. 1003, ¶¶ [0098], [0127]; Ex. 1002 ¶ 124. Fig. 1F1 (below), for example, further shows that the adherent patch and its backing comprise an hourglass shape with two ends joined by a narrower midsection. *See* Ex. 1003, ¶ [0093] Ex. 1002, ¶ 124. Furthermore, while Fig. 1F1 shows a top view, the cross-section of Fig. 1I1 (below) shows that backing 111 on the bottom of the device extends to the full width of top layer 164. Thus, a POSITA would understand that Mazar discloses an elongated strip with a mid-section that connects and is narrower than two ends of the backing. Ex. 1002. ¶ 124.

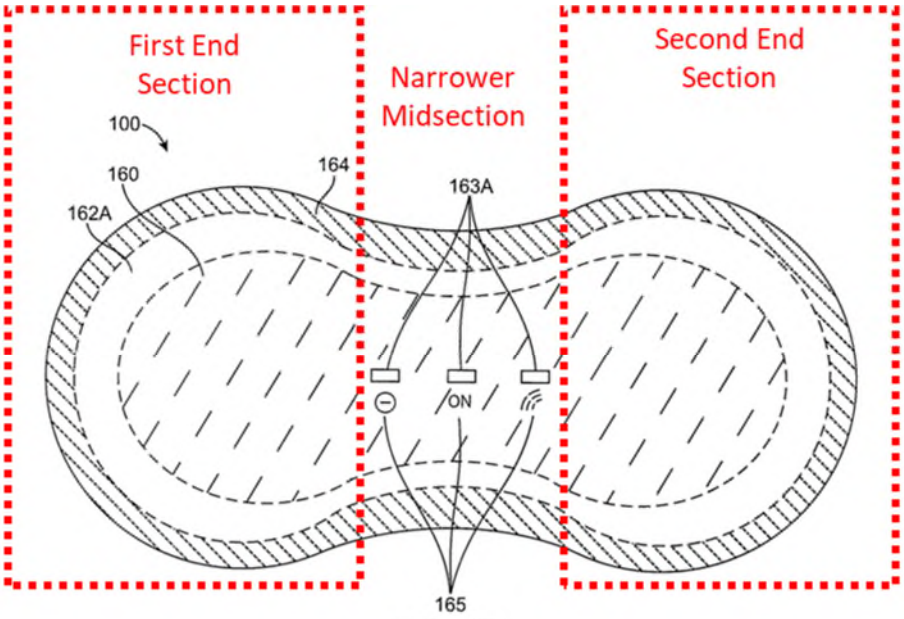



FIG. 1F1

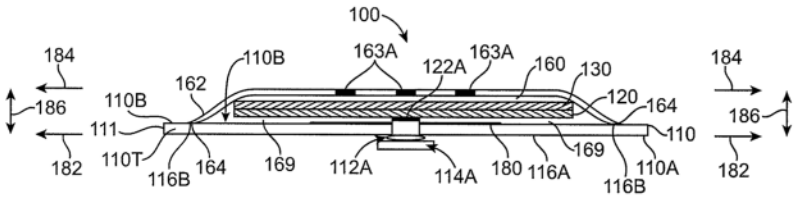



FIG. 1I1

Moreover, the Examiner correctly recognized that a narrowed mid-section is obvious because "[t]he skilled artisan would recognize narrowing a mid-section between the two ends of a backing obviously reduces weight by eliminating unnecessary material." Ex. 1007, p. 178 (January 25, 2021, Office Action); Ex. 1002, ¶ 125. Thus, it would similarly be obvious to a POSITA to use a narrowing in a patch combining the teachings of *Mazar* and *Yang* for that reason. Ex. 1002, ¶ 125. *Mazar* also discloses a backing that is an elongated strip. A POSITA would

view an elongated strip design as a "standard of care" and common sense. Ex. 1002, ¶ 125. Most clinically-used monitors have an elongated strip design—even implantable recorders are elongated in shape. *Id*. Thus, a POSITA would understand that *Mazar* discloses an elongated strip with a mid-section that connects and is narrower than two ends of the backing. *Id*. This is because in addition to the reduction of weight and the elimination of unnecessary material, reducing excess material will increase patient comfort by reducing the area covered by the patch and allowing patch to twist more easily and therefore conform to the movement of the patient. *Id*.

A POSITA would further understand that *Yang* discloses a backing comprising an elongated strip with two ends. Ex. 1002, ¶ 126. The fact that both *Mazar* and *Yang* relate to patches shaped as elongated strips further demonstrates their compatibility. *Id*. *Mazar* further shows patch backings with and without narrowing, further showing the compatibility of the two designs. *Id*.

**c) Element [1-B]**

*Mazar* and *Yang* disclose "an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals." *Mazar* expressly teaches that the patch comprises two electrodes to measure the ECG of the patient. Ex. 1003, ¶ [0098]; Fig. 1B; Ex. 1002, ¶ 128. As shown, for example, in Fig. 1B, at least **two electrodes** (*e.g.*, **112A and 112D**) are positioned on each end of the backing of the

adherent patch:

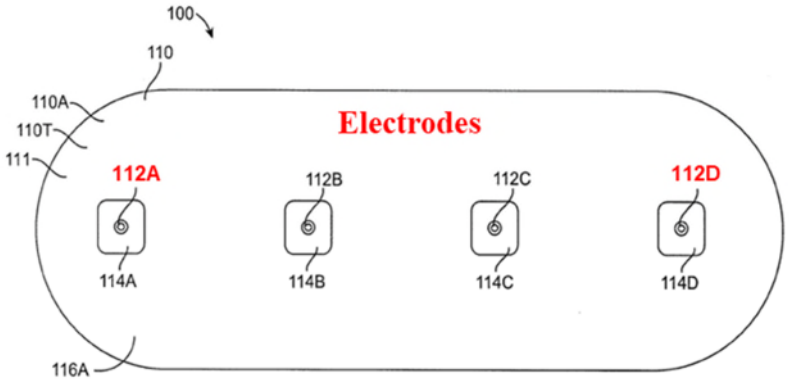



FIG. 1B

A POSITA would understand that at least *Mazar* discloses this element and that it would be obvious to employ electrodes on each end of the backing in its various embodiments. Ex. 1002, ¶¶ 30, 62, 128, 129.

Further, demonstrating the fact that the number of electrodes can be varied to achieve trade-offs between complexity, cost and functionality, *Yang* discloses an embodiment with just **two electrodes 310** positioned on each end of the backing of the adherent patch. Ex. 1005, 3:2-4, 63-4:2, Fig. 3 (reproduced below); Ex. 1002, ¶ 130. Placing two electrodes on opposite ends of the backings optimizes the spread of the electrodes, while minimizing the cost and complexity that would arise from adding more than two electrodes. Ex. 1002, ¶ 130.

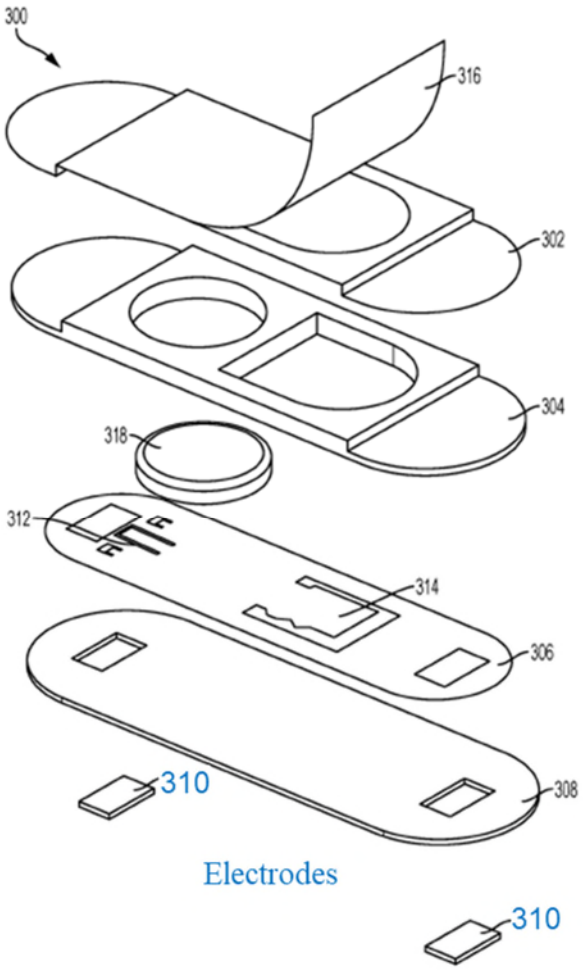



FIG. 3

A skilled artisan would view an electrocardiographic electrode on each end of the backing as a "standard of care." Ex. 1002, ¶ 131. Thus, POSITA would understand that *Mazar* and *Yang*, either alone or in combination, discloses this element. *Id*.

**d) Element [1-C]**

*Mazar* discloses "a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes." *Mazar* expressly

teaches a **flex printed circuit board 120** includes a pair of **traces 123A, 123D** to connect to electrodes 112A, 112D, respectively. Ex. 1003, ¶ [0100]; Fig. 1D; Ex. 1002, ¶ 133.

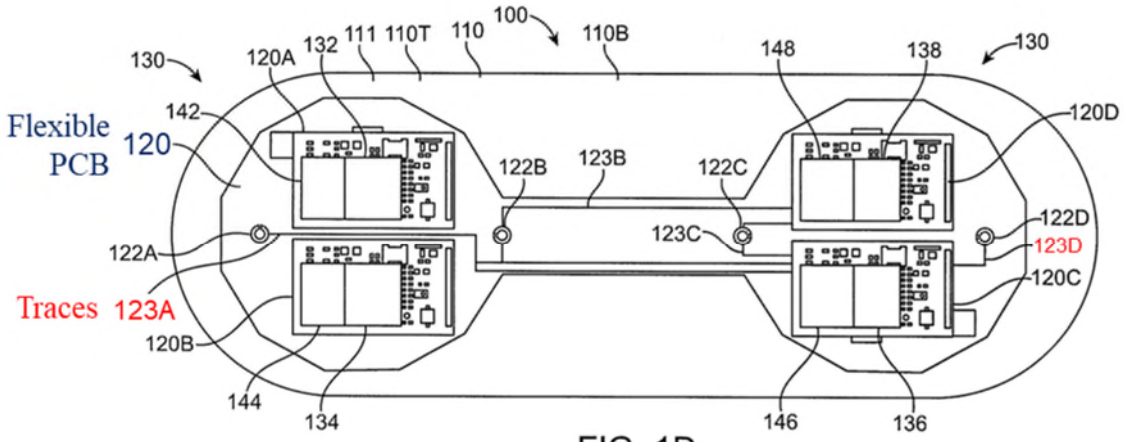



FIG. 1D

132.135. It is well understood that a circuit trace is necessary to connect to the electrodes to the processor to record the relevant data. Ex. 1002, ¶134. A POSITA would understand that *Mazar* discloses this element. *Id*.

*Yang* similarly teaches a flexible PCB 306 coupled to a top foam layer 304 and a bottom foam layer 308. Ex. 1005, 3:63-4:2, Fig. 3 (reproduced below); Ex. 1002, ¶ 135.

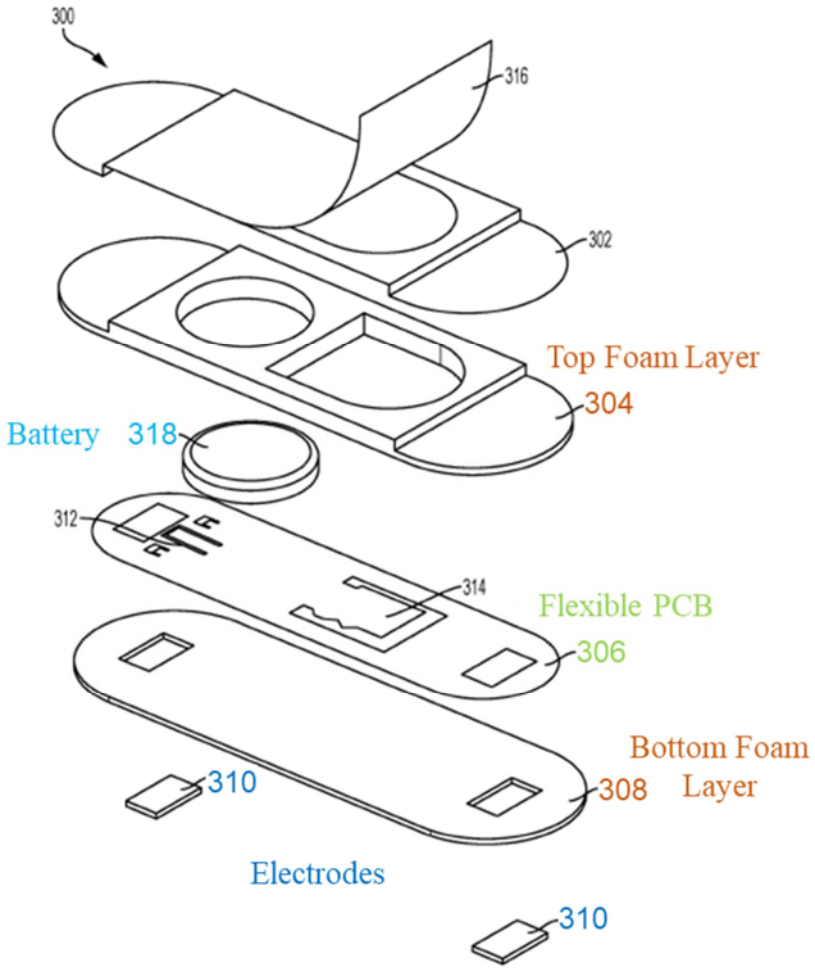



FIG. 3

The flexible PCB 306 is coupled to at least two electrodes 310 and enables the disposable module 300 to conform and to adhere to a user's movements. Ex. 1005, 4:2-4; Ex. 1002, ¶ 136. *Yang* also teaches that the flexible PCB 306 and bottom foam layer 308 each have two openings to allow for the coupling of the at least two electrodes 310 to the flexible PCB 306. Ex. 1005, 4:39-42; Ex. 1002, ¶ 136. A POSITA would readily understand that *Yang's* teaching to provide an electrical coupling of the electrodes to the PCB would necessarily include a pair of circuit

traces, such as taught by *Mazar*. Ex. 1002, ¶ 136. All electronic devices, including those used in cardiac electrophysiology such as ablation and recording catheters and pacemakers and defibrillators, have circuit traces on their circuit boards. *Id*. Indeed, a printed circuit board is, by definition, a board with printed traces to connect circuit elements. *Id*.

A POSITA would understand that *Mazar* and *Yang*, either alone or in combination, discloses this element. Ex. 1002, ¶ 137.

**e) Element [1-D]**

*Mazar* and *Yang* disclose "a wireless transceiver to communicate at least a portion of the electrocardiographic signals." *Mazar* teaches that the device 100 can include electronics components 130, such as a wireless communications circuitry 132. Ex. 1003, ¶¶ [0104], [0105]; Ex. 1002, ¶ 139. Specifically, *Mazar* discloses that the "wireless communication circuitry is configured to transmit the hydration signal, the electrocardiogram signal and the inclination signal to the remote center with a single wireless hop, for example from wireless communication circuitry 132 to intermediate device 102." Ex. 1003, ¶ [0105]; Ex. 1002, ¶ 139. Similarly, *Yang* discloses a wireless sensor. Ex. 1005, 2:48-55; Ex. 1002, ¶ 139. Wireless communication of cardiac electrical signals existed in implantable devices well before 2013. Ex. 1002, ¶ 139. A POSITA would understand that *Mazar* and *Yang* discloses this element. Ex. 1002, ¶ 139.

### 2. Independent Claim 11

Claim 11 is an independent claim that differs from Claim 1 as shown in the comparison below.

| Claim 1 | Claim 11 |
|---|---|
| An electrocardiography patch, comprising:<br><br>a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing;<br><br>an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;<br><br>a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes; and<br><br>a wireless transceiver to communicate at least a portion of the electrocardiographic signals. | An electrocardiography monitor, comprising:<br><br>a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing;<br><br>an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;<br><br>a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes;<br><br>a wireless transceiver to communicate at least a portion of the electrocardiographic signals;<br><br>a battery on one of the ends of the backing;<br><br>a processor powered by the battery; and<br><br>memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals. |

As can be seen from the table, the only material difference between claims 1

and 11 is the further recitation of basic elements required to make a wireless patch function, namely, the battery, the processor, and the memory. These basic elements are disclosed in the prior art shown below. Moreover, although the preamble slightly deviates between claims 1 and 11, a POSITA would understand that the electrocardiographic patch claimed by Claim 1 is an electrocardiographic monitor of Claim 11 and, thus, the different words in the preamble do not materially change the scope of preambles between Claims 1 and 11. Ex. 1002, ¶¶ 115-117, 140.

**a) Element [11-E]**

*Mazar* and *Yang* disclose "a battery on one of the ends of the backing." *Mazar* discloses that the device 100 includes a battery coupled to the electronic components. Ex. 1003, ¶¶ [0031], [0033], [0094]; Ex. 1002, ¶ 141. For example, Fig. 1E shows **batteries 150** positioned over the flex printed circuit board and electronic components, which are on the left and right ends of the backing. Ex. 1003, ¶¶ [0113], [0094], [0064]; Ex. 1002, ¶ 141. Like the '743 patent, these batteries are intended to be removed and/or replaced when the replaceable patch is replaced. *Id*. A POSITA would understand that *Mazar* discloses this element. Ex. 1002, ¶ 141.

Furthermore, while *Mazar* discloses that an air gap "may" be present between the patch 110 and the printed circuit board, a POSITA would understand

that teaching to be optional, as the language expressly states. Ex. 1003, ¶ [0145]; Ex. 1002, ¶ 142. For example, while the air gap might enhance breathability, the failure to secure the printed circuit board to the backing could result in discomfort as the printed circuit board and backing move separately and stress one another. Ex. 1002, ¶ 142. This movement between the electrode and backing could also cause the metal in the electrode to introduce wear or tears in the backing. *Id*. Thus, a POSITA would find it obvious to alternatively use the arrangement in *Yang* where the battery 318 is positioned directly on the flexible PCB 306, which is on the backing 308 with no intervening air gap. Ex. 1005, 3: 63-4:2, 4:28-38, Fig. 3 (reproduced below); Ex. 1002, ¶ 142. Furthermore, putting the battery on the ends of the backing, rather than the middle, is a simple design choice that can be readily selected by a POSITA. Ex. 1002, ¶ 142. This placement would be particularly obvious in a patch with a narrowed middle, which would reduce the space available for a battery. *Id*.

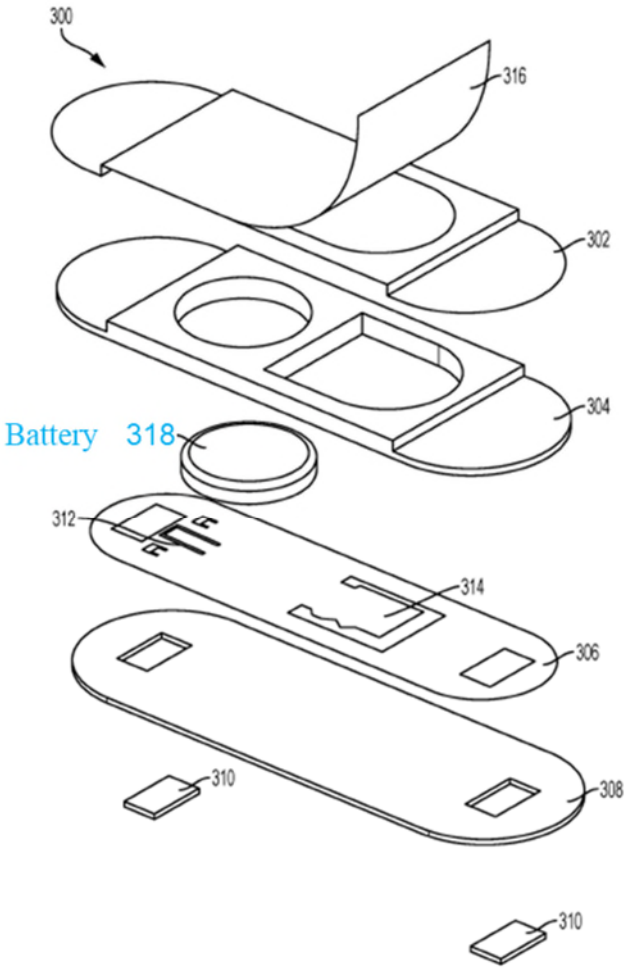



FIG. 3

Just like the '743 patent, *Yang* teaches that its battery 318 is housed on the replaceable portion of its patch (the disposable module 102 of *Yang* and/or the replaceable extended wear electrode patch of the '743 patent) and on one end of the backing. Ex. 1005, Fig. 3, 3:63-4:2, 4:28-38; Ex. 1002, ¶ 143. And similar to the '743 patent, *Yang* also teaches that its health monitoring device is cost-efficient because the reusable portion can be separated from the disposable portion (which houses the battery) and fitted with a new replacement disposable portion to extend

its lifetime. Ex. 1005, 5:41-53; Ex. 1002, ¶ 143. A POSITA would readily understand that *Yang's* teaching to reuse elements of the patch (such as the electronics) and replace other elements of the patch (such as the battery and the patch body), would improve the cost effectiveness of a disposable portion of a health monitoring device, such as that of *Mazar*, which would include the consumable battery and create a product that is less wasteful. Ex. 1002, ¶ 143.

A POSITA would understand that *Mazar* and *Yang*, either alone or in combination, discloses this element. Ex. 1002, ¶ 144.

**b) Element [11-F]**

*Mazar* and *Yang* disclose "a processor powered by the battery." *Mazar* teaches that the device 100 includes a processor 262 that is powered by the battery. Ex. 1003, ¶ [0167]; Ex. 1002, ¶ 145. A POSITA would understand that at least *Mazar* discloses this element. Ex. 1002, ¶ 145.

Yang similarly discloses an electrical component unit 510 for "processing of information collected by the at least two electrodes." Ex. 1005 4:67-4; Ex. 1002, ¶ 145. A POSITA would understand that the most obvious way to embody this through a processor that is powered by the battery. Ex. 1002, ¶ 145. Thus, a POSITA would understand that the combination of *Mazar* and *Yang* along with the commonsense knowledge of a POSITA discloses this element. Ex. 1002, ¶ 145.

**c) Element [11-G]**

*Mazar* discloses "memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals." *Mazar* teaches that the device 100 includes a memory in communication with a processor for storing the physiological signals. Ex. 1003, ¶¶ [0048], [0095], [0104]; Ex. 1002, ¶ 146. The storage of samples of cardiac electrical signals has long been understood and practiced for decades. *See*, *e.g.*, Ex. 1005 5:23-31 (explaining a POSITA would recognize the suitable addition of memory to the disclosed patch); Ex. 1002, ¶ 146. A POSITA would understand that at least *Mazar* discloses this element and that it would be an obvious addition to an electrocardiograph monitor. Ex. 1002, ¶ 146. Moreover, the common typical operation of a processor requires corresponding memory that stores data while it is being input, output, and processed by the processor. *Id*. Thus, storing data such as cardiac signals in a processor based system is the most obvious thing to do. *Id*.

**3. Claims 2 and 12**

Claim 2 depends on Claim 1 and further requires that the ECG patch includes "an accelerometer provided on the backing." Similarly, Claim 12 depends on Claim 11 and further requires that there is "an accelerometer provided on the backing."

In addition to the electrodes, *Mazar* teaches that the device 100 can include

electronics components 130, such as an activity sensor and activity circuitry 134. Ex. 1003, ¶¶ [0015], [0107]; Ex. 1002, ¶ 148. Specifically, *Mazar* confirms that the activity sensor and activity circuitry 134 can comprise many known activity sensors and circuitry, such as, an accelerometer, a piezoelectric accelerometer, capacitive accelerometer, or an electromechanical accelerometer. *Id*. Activity sensors have long been understood and practiced for decades. Ex. 1002, ¶ 148. A POSITA would understand that *Mazar* discloses this element and given the popularity of the quantified life movement by the priority date of the '743 it would be obvious to a POSITA to include an accelerometer in this sort of patch. Ex. 1002, ¶ 148.

**4. Claims 3 and 13**

Claim 3 depends on claim 1 and further requires that the ECG patch includes "a physiology sensor provided on the backing to measure body temperature." Similarly, Claim 13 depends on Claim 11 and further requires "a physiology sensor provided on the backing to measure body temperature."

*Mazar* expressly teaches that the device 100 can include electronics components 130 and a memory for storing physiologic signals. Ex. 1003, ¶¶ [0048], [0095]; Ex. 1002, ¶ 150. Specifically, *Mazar* enumerates several examples that include a temperature sensor. *Id*. Temperature sensors have long been understood and practiced for decades. Ex. 1002, ¶ 150 (citing Ex. 1008-

1009). A POSITA would understand that at least *Mazar* discloses this element and given the popularity of the quantified life movement by the priority date of the '743 it would be obvious to a POSITA to include a temperature sensor in this sort of patch. Ex. 1002, ¶ 150.

**5. Claims 4 and 14**

Claim 4 depends on claim 1 and further requires that "each of the ends of the backing is rounded on an outer edge." Claim 14 depends on claim 11 and further requires "each of the ends of the backing [to be] rounded on an outer edge."

*Mazar* discloses that the device 100 can comprise many shapes, such as a dog bone or an hourglass, which shapes are rounded on the outer edges. Ex. 1003, ¶ [0093]; Fig. 1F1; Ex. 1002, ¶152. A POSITA would understand that at least *Mazar* discloses this element. Ex. 1002, ¶152. It would be obvious to use rounded edges for comfort of the patient and for aesthetic reasons. *Id*. For example, the corners of squared off edges have a tendence to peel off since they come to a point. *Id*.

**6. Claims 5 and 15**

Claim 5 depends on claim 1 and further requires "a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level." Claim 15 depends on claim 11 and further requires "a physiology

and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned, and estimated blood glucose level."

Like claims 3 and 13, *Mazar* expressly teaches that the device 100 can include electronics components 130 and a memory for storing physiologic signals. Ex. 1003, ¶¶ [0013], [0014], [0048], [0095]; Ex. 1002, ¶154. Specifically, *Mazar* teaches that the plurality of sensors include a heart rate sensor, a blood pressure sensor, a sleep sensor, a temperature sensor, and so on, as claimed. *Id*. Physiology and activity sensors measuring one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level have long been understood and practiced for decades. Ex. 1002, ¶ 154 (citing Ex. 1008-1012). A POSITA would understand that at least Mazar discloses this element and, given the popularity of the quantified life movement by the priority date of the '743, it would be obvious to a POSITA to include these sorts of sensors in this sort of patch. Ex. 1002, ¶ 154.

**7. Claims 6 and 16**

Claim 6 depends on claim 1 and further requires that "the electrocardiographic signals are converted to a different format and processed." Claim 16 depends on claim 11 and further requires "the electrocardiographic signals [to be] converted to a different format and processed."

*Mazar* discloses that the device 100 includes a processor configured to process data received from the sensors and to display information regarding the data. Ex. 1003, ¶¶ [0013], [0104]; Ex. 1002, ¶ 156. Specifically, *Mazar* teaches that at step 435, the signals from the sensors are processed in many known ways, for example, to generate at least one of a derived signal, a time averaged signal, a filtered signal, or so on. Ex. 1003, ¶¶ [0013], [0104], [0197]; Ex. 1002, ¶ 156. *Mazar* further discloses that at step 445, these processed signals are transmitted to a remote site. Ex. 1003, ¶¶ [0013], [0104], [0199]; Ex. 1002, ¶ 156. The conversion of electrocardiographic signals to a different format and processed has long been understood and practiced for decades. Ex. 1002, ¶ 156 (citing Ex. 1008, 1013). A POSITA would understand that at least *Mazar* discloses this element. Ex. 1002, ¶ 156.

**8. Claims 7 and 17**

Claim 7 depends on claim 6, which depends on claim 1, and further recites that "the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver." Claim 17 depends on claim 16, which depends on claim 11, and further requires that "the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver."

As described with reference to Claims 6 and 16, measurement signals, which

can include derived and/or processed measurement signals, are transmitted to a remote site, such as a remote processor 106P, which comprises a client computer or a backend server, as claimed. Ex. 1003, ¶¶ [0013], [0104], [0091], [0197], [0199]; Ex. 1002, ¶158. The retrieving of the formatted electrocardiographic signals has long been understood and practiced for decades. Ex. 1002, ¶ 158 (citing Ex. 1008). Furthermore, by their nature, wireless patches send data to a computer for processing, otherwise the wireless transmission would be lost. Ex. 1002, ¶ 158. As such, this is an obvious feature that is commonly present in wireless patches. *Id*. A POSITA would understand that at least *Mazar* discloses this element. *Id*.

**9. Claims 8 and 18**

Claim 8 depends on claim 1 and further recites that "the electrodes are exposed on a contact surface of the backing." Claim 18 depends on claim 11 and similarly requires that "the electrodes are exposed on a contact surface of the backing."

*Mazar* discloses that the electrodes can be fabricated in many ways, including being printed on a flexible connector and/or exposed to the gel through apertures of breathable tape such that the gel can be positioned over the electrodes and portions of breathable tope for coupling the electrodes to the skin of the patient. Ex. 1003, ¶¶ [0122], [0133]; Ex. 1002, ¶ 160. Moreover, exposing the

electrodes on the bottom of the patch is the most obvious way to allow them to make contact with the patient and record the ECG signals. *Id*. Thus, this is the epitome of an obvious feature for this sort of device. *Id*. A POSITA would understand that at least *Mazar* discloses this element. *Id*.

**10. Claims 9 and 19**

Claim 9 depends on claim 1 and further requires that the ECG patch includes "a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing." Claim 19 depends on claim 11 and further requires "a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing."

*Mazar* expressly teaches that an adhesive 116A can be disposed on the underside/contact side of the patch 11. Ex. 1003, ¶ [0128]; Ex. 1002, ¶ 162. And that the adhesive 116A includes a hydrocolloid adhesive, as claimed. *Id*. Furthermore, a POSITA would understand that it is well known for hydrocolloid adhesives to be used in medical applications to avoid skin irritation. Ex. 1002, ¶ 162. Hydrocolloids were one of a few commonly used adhesives for this sort of application. *Id*. Nevertheless, a POSITA would understand that at least *Mazar* discloses this element. Ex. 1002, ¶163. And that it is obvious to use hydrocolloid adhesives to attach electrode patches to a patient's skin. *Id*.

**11. Claims 10 and 20**

Claim 10 depends on claim 9, which depends on claim 1, and further recites

that "the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface." Claim 20 depends on claim 19, which depends on claim 11, and further requires that "the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface."

*Mazar* discloses an adhesive 116A, which is at least formed on the ends of the backing on the contact surface as claimed. Ex. 1003, ¶ [0128]; Ex. 1002, ¶165. A POSITA would understand that *Mazar* discloses this element. Ex. 1002, ¶165.

A POSITA would further understand that the placement of the hydrocolloid adhesive is a simple design choice that was already well-known in the prior art. Ex. 1002, ¶ 166. For example, *Yang* shows a bottom foam layer 308 that includes a double adhesive layer positioned directly on one end of the backing of the adherent patch (*e.g.*, the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306) to adhere both to the flexible PCB 306 and to a user at the same time. Ex. 1005, 4:9-15, Fig. 3 (reproduced below); Ex. 1002, ¶166.

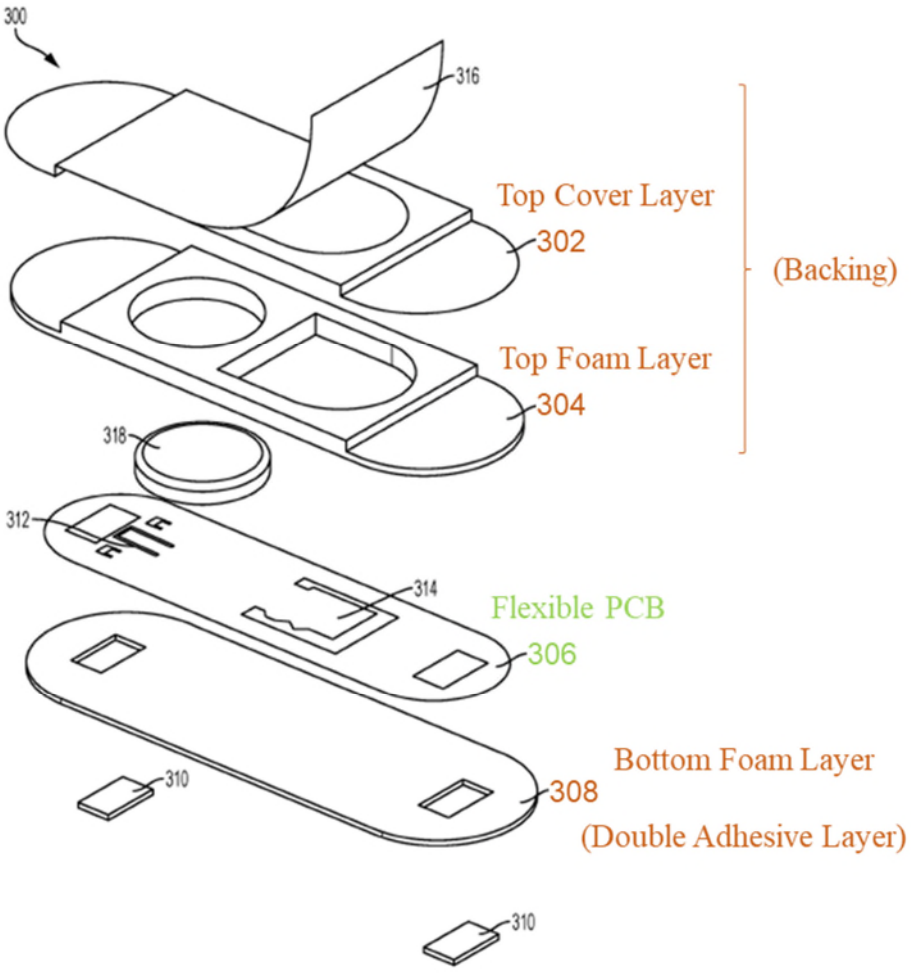



FIG. 3

Furthermore, just like the '743 patent, *Yang* teaches that its "patch" looks like a "band-aid" and adheres to the user's body as such. Ex. 1005, 2:50-55; Ex. 1002, ¶ 167. Skilled artisans have known for decades that even transient exposure to an ECG patch can cause dermatitis and that longer exposure makes it even worse. Ex. 1002, ¶ 167. This supports the obvious design choice of limiting the adhesive usage to the ends of the patch and not the middle. *Id*. Moreover, placing adhesive on the ends of the backing is the most obvious choice because if the ends are not

adhered, it is more likely they will peel up and cause the adhesive contact to weaken. *Id*. A POSITA would readily understand that this principle of providing irritation free adhesives for biomedical use only on the ends of the backing, on a contact surface, as claimed, is expressly taught by the "band-aid" analogy taught by *Yang*. *Id*.

A POSITA would understand that *Mazar* and *Yang*, either alone or in combination, discloses this element. Ex. 1002, ¶ 168.

### B. GROUND 2: Oster in view of Yang Renders Claims 1-20 Obvious

A POSITA would have found it obvious to predictably combine *Oster's* adherent patch device with the teachings of *Yang* to achieve the particular design objectives in *Oster's* system, as explained in Section VI.E above. Ex. 1002 ¶¶ 98-104.

#### 1. Independent Claim 1

*Oster* and *Yang* disclose the method of Claim 1 as described below with reference to the Claim element designations. *See* Section V.E.

##### a) Element [1-PRE]

*Oster* and *Yang* disclose "[a]n electrocardiography patch." *Oster* discloses a **biomedical sensor system** for use in diagnostic procedures, including monitoring the electrical activity of a subject's heart, for example, in developing an electrocardiogram (ECG). Ex. 1004, ¶¶ [0021], [0028]; Figs. 1, 2; Ex. 1002, ¶ 172.

Similarly, *Yang* also discloses a modular wearable sensor device in a "patch" form that is attached to the user for health monitoring, such as for ECG measurements. Ex. 1005, 2:24-50; Ex. 1002, ¶ 172.

A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element. Ex. 1002, ¶ 173.

**b) Element [1-A]**

*Oster* and *Yang* disclose "a backing comprising an elongated strip with a mid-section connecting two ends of the backing." And *Oster* further discloses its elongated patch as having a "mid-section [that] is narrower than the two ends of the backing." Fig. 1 (below), for example, shows that the biomedical sensor system 100 comprises a hub electrode 102, two satellite electrodes 104, and two connectors 106 positioned to couple each satellite electrode 104 to the hub 102. Ex. 1004, ¶¶ [0031], [0034-35], [0051], [0052], [0062]; Fig. 1; Ex. 1002, ¶ 175.

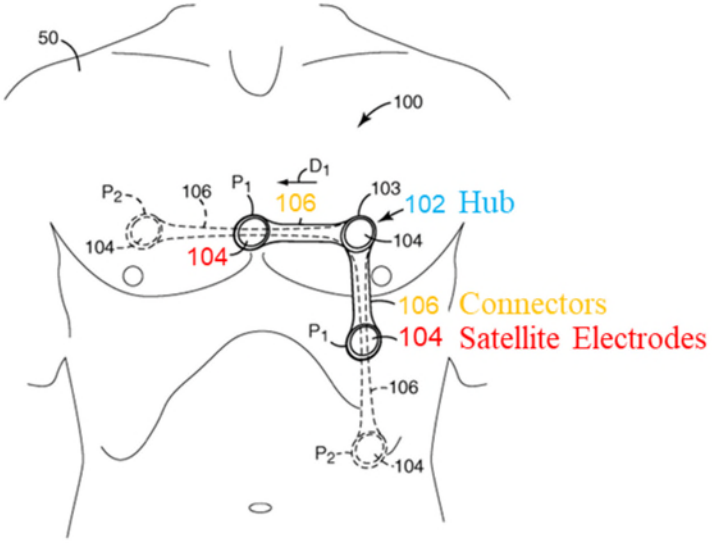



*Fig. 1*

As shown in more detail in Fig. 2, each connector 106 comprises a wire conductor 162 (*e.g.*, a copper wire) positioned between **a first support member 164,** and **a second support member 166** to provide an electrical communication pathway between the hub 102 and the electrode 104. Ex. 1004, ¶ [0057]; Ex. 1002, ¶ 176. One or more of the support members 164, 166, are the "backing" of the connector 106. Ex. 1004, ¶ [0062]; Ex. 1002, ¶ 176.

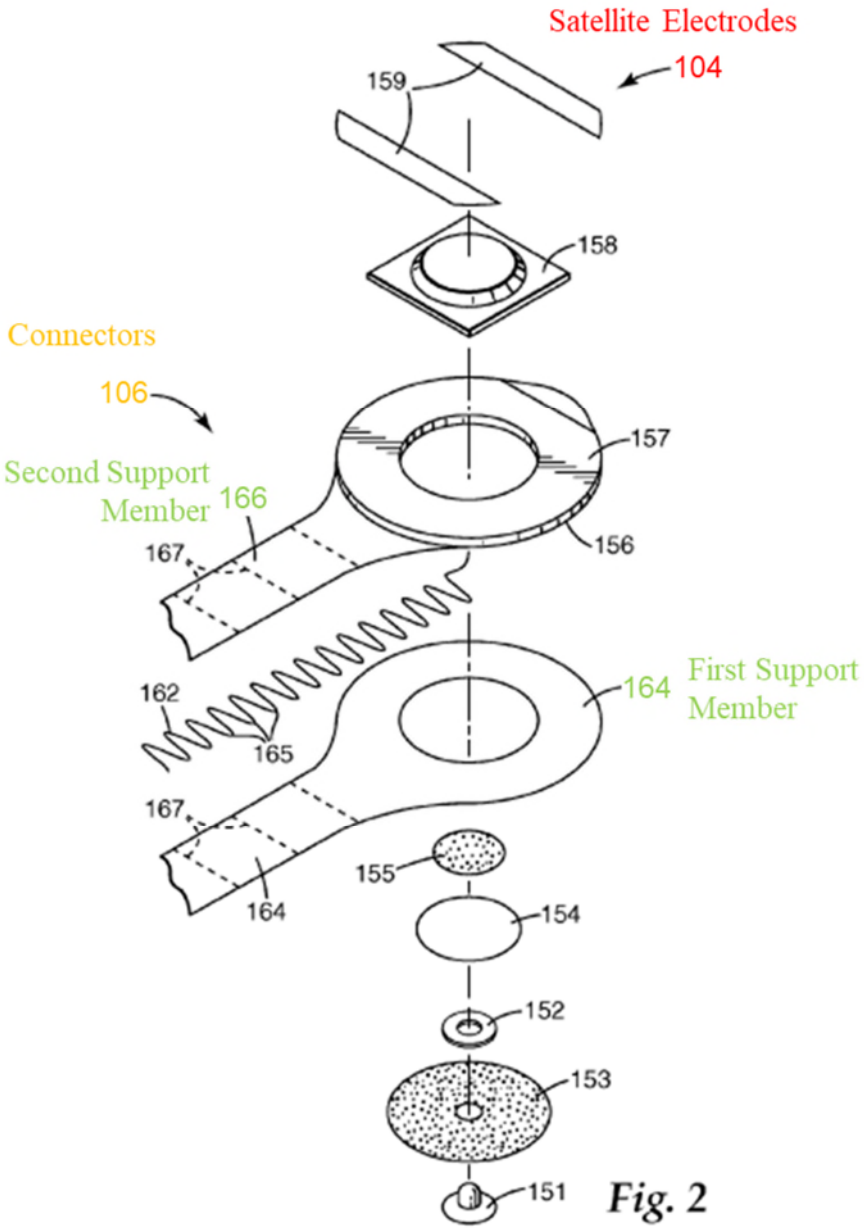



*Fig. 2*

As shown in Fig. 1, the ends 104 of the biomedical sensor system 100 are wider than the connector 106, which narrows compared to the ends, as this claim element requires. Ex. 1002, ¶ 177. As shown in Fig. 2, support members 164, 166, disclose a backing comprising an elongated strip with a mid-section connecting two ends of the backing (where the electrodes 104 and/or hub 102

reside), wherein the mid-section is narrower than the two ends of the backing. *Id*. In other words, *Oster's* three node embodiment meets this limitation in a variety of ways. Ex. 1002, ¶ 177. Electrodes 104 could be considered to be the ends, which narrow in the connectors to hub electrode 102. *See,* Ex. 1004, ¶ [0035]; Ex. 1002, ¶ 177. Alternately, one could consider just the hub electrode 102 and one satellite electrode 104. Ex. 1002, ¶ 177.

179. Moreover, the patent examiner correctly recognized that a narrowed mid-section is obvious because "[t]he skilled artisan would recognize narrowing a mid-section between the two ends of a backing obviously reduces weight by eliminating unnecessary material." Ex. 1007, p. 178 (January 25, 2021, Office Action). A POSITA would view an elongated strip design as a "standard of care." Ex. 1002, ¶ 178. Most clinically used monitors have an elongated strip design—even implantable recorders are elongated in shape. *Id*. This is because in addition to the reduction of weight and the elimination of unnecessary material, reducing excess material will increase patient comfort by reducing the area covered by the patch and allowing patch to twist more easily and therefore conform to the movement of the patient. *Id*. Thus, a POSITA would understand that at least *Oster* expressly discloses this element and that it would be obvious to a POSITA to include this element in a patch. *Id*.

A POSITA would further understand that *Yang* discloses a backing

comprising an elongated strip. Ex. 1005, 3:63-4:2, Fig. 3 (reproduced below); Ex. 1002, ¶ 179.

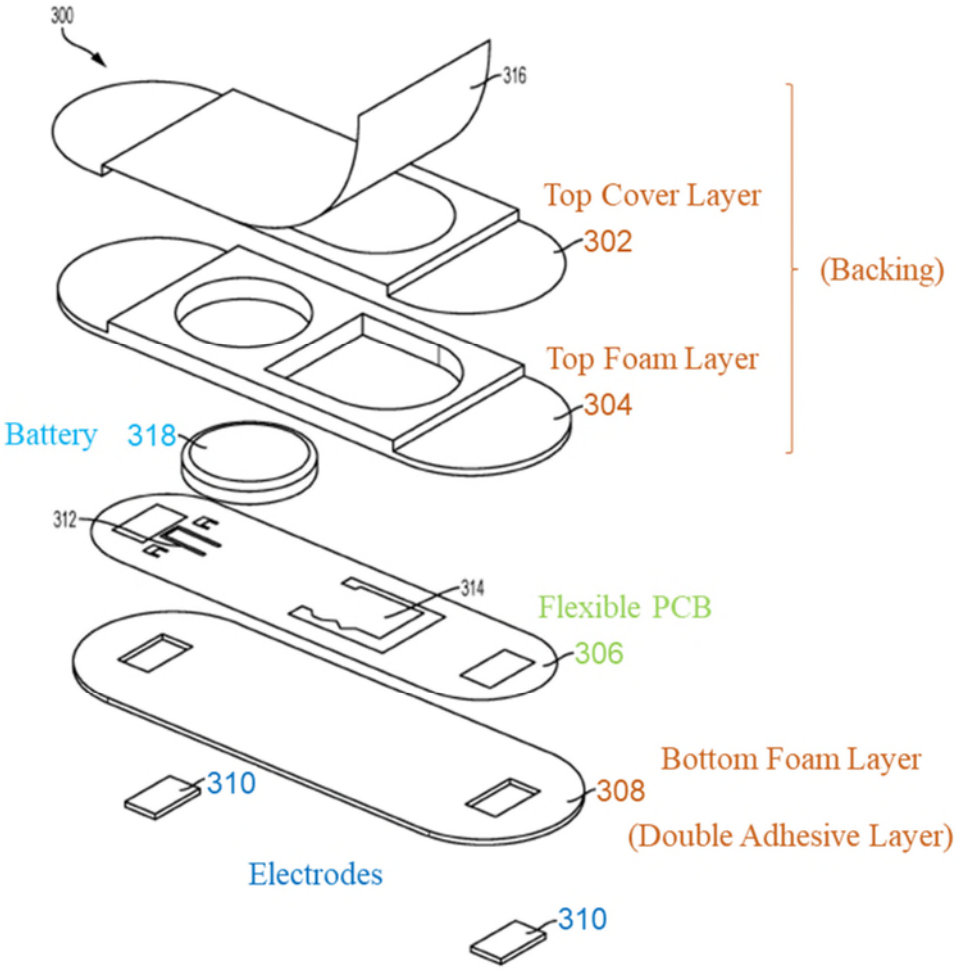



FIG. 3

**c) Element [1-B]**

*Oster* and *Yang* disclose "an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals." As shown in Fig. 1 above, the biomedical sensor system 100 includes a hub electrode 102, **two satellite electrodes 104** on each terminal end of the system 100, and two connectors 106

positioned to couple each satellite electrode 104 to the hub 102. Ex. 1004, ¶¶ [0031], [0035], [0043]; Fig. 1; Ex. 1002, ¶ 181.

*Oster* teaches that its biomedical sensor system 100, like the '743 patent, is for monitoring the electrocardiographic signals from the subject's heart, for example, in developing an electrocardiogram (ECG). Ex. 1004, ¶ [0028]; Ex. 1002, ¶ 182. *Oster* explains that it is well known in the art for an ECG to be captured using a variety of electrode lead configurations, including a variety of 3-lead and 5-lead ECG configurations. Ex. 1004, ¶ [0029]; Ex. 1002, ¶ 182. A POSITA would also understand that it would have been obvious or well-known to apply the teachings of *Oster* to any other lead configuration, such as the two-electrode configuration of *Yang*, which would reduce cost and aid in simplicity. Ex. 1004, ¶ [0029], Ex. 1002, ¶ 182. Moreover, in its 3-lead embodiment as disclosed in the Fig. 1, *Oster's* patch with its triangular shape would effectively have three ends. Ex. 1002, ¶ 182.

*Yang* discloses an embodiment with just two electrodes 310 positioned only on each end of the backing of the adherent patch (e.g., the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306). Ex. 1005, 3:2-4, 63-4:2, Fig. 3 (reproduced below); Ex. 1002, ¶ 183. Further, demonstrating the fact that the number of electrodes can be varied to achieve trade-offs between complexity, cost and functionality. Ex. 1002, ¶ 183. Placing two electrodes on

opposite ends of the backings optimizes the spread of the electrodes, while minimizing the cost and complexity that would arise from adding more than two electrodes. Ex. 1002, ¶ 183.

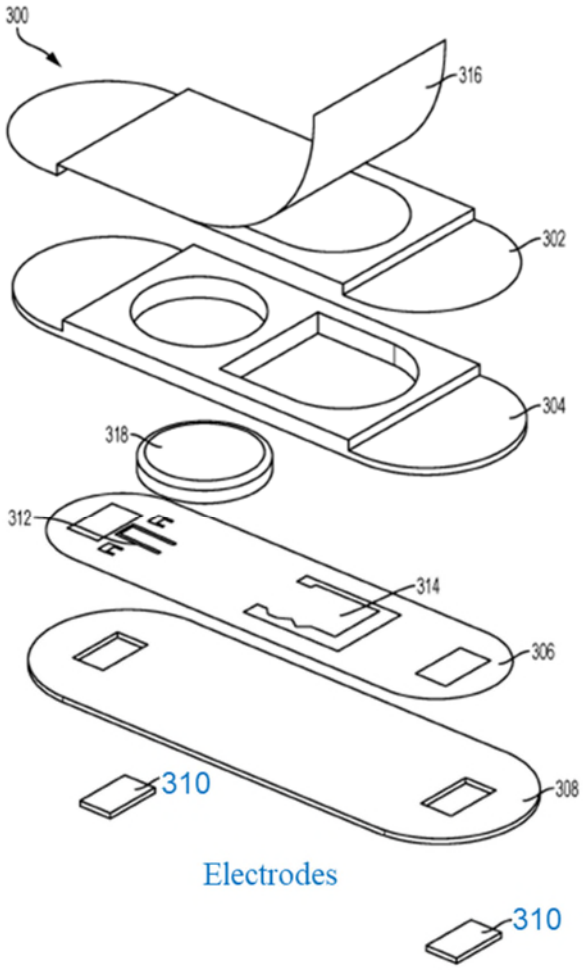



FIG. 3

A skilled artisan would view an electrocardiographic electrode on each end of the backing as a "standard of care." Ex. 1002, ¶ 184. Thus, a POSITA would understand that *Oster* discloses this element and that it would be obvious to employ electrodes on each end of the backing in its various embodiments in view

of *Yang*, which presents a simpler two electrode patch. *Id*.

**d) Element [1-C]**

*Oster* discloses "a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes." As shown in Fig. 1 above, *Oster* teaches that the biomedical sensor system 100 includes a hub 102, two satellite electrodes 104, and **two connectors 106** positioned to couple each satellite electrode 104 to the hub 102. Ex. 1004, ¶¶ [0028], [0031], [0043], [0051], [0052]; Fig. 1; Ex. 1002, ¶ 186. The connectors 106 are adapted to provide a pathway between the electrodes 104 (or other sensors) and the hub 102 for one or more signals that may be communicated between the electrodes 104 and the hub 102. *Id*.

The biomedical sensor system 100 is size-configurable and conformable to the subject 50, at least partially because the connector 106 is partially formed of a viscoelastic material, such that by applying force to the connector 106 substantially along the length of the connector 106 (*e.g.*, substantially oriented in the first direction $D_1$), the connector 106 can be elongated. Ex. 1004, ¶ [0051]; Ex. 1002, ¶ 187. The connector 106 includes **a wire conductor 162** (*e.g.*, a copper wire) positioned between a first support member 164, and a second support member 166 **to provide an electrical communication pathway between the hub 102 and the electrode 104**. Ex. 1004, ¶¶ [0028], [0057]; Ex. 1002, ¶ 187.

It is well understood that a circuit trace is necessary to connect to the electrodes to the processor to record the relevant data. Ex. 1002, ¶ 188. A POSITA would understand that *Oster* discloses this element. *Id.*

The use of flexible PCBs was very common in these applications. Ex. 1002, ¶ 189. And *Yang* similarly teaches a flexible PCB 306 coupled to a top foam layer 304 and a bottom foam layer 308. Ex. 1005, 3:63-4:2, Fig. 3 (reproduced below); Ex. 1002, ¶ 189.

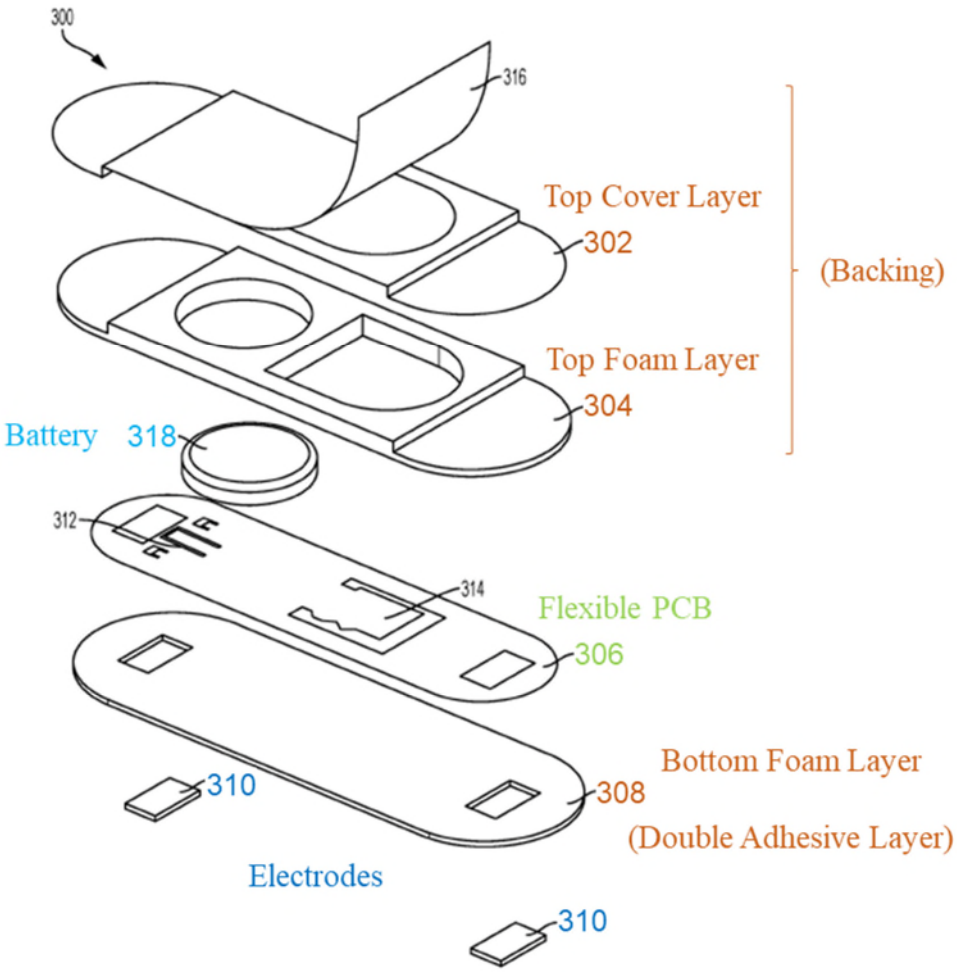



FIG. 3

The flexible PCB 306 is coupled to at least two electrodes 310 and enables the disposable module 300 to conform and to adhere to a user's movements. Ex. 1005, 4:2-4; Ex. 1002, ¶ 190. *Yang* also teaches that the flexible PCB 306 and bottom foam layer 308 each have two openings to allow for the coupling of the at least two electrodes 310 to the flexible PCB 306. Ex. 1005, 4:39-42; Ex. 1002, ¶ 190. A POSITA would readily understand that *Yang's* teaching to provide an electrical coupling of the electrodes to the PCB would necessarily include a pair of circuit traces, such as taught by *Oster*. Ex. 1002, ¶ 190. All electronic devices, including those used in cardiac electrophysiology such as ablation and recording catheters and pacemakers and defibrillators, have circuit traces. *Id*.

A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element. Ex. 1002, ¶ 191.

**e) Element [1-D]**

*Oster* and *Yang* disclose "a wireless transceiver to communicate at least a portion of the electrocardiographic signals." *Oster* expressly teaches that the hub 102 can wirelessly communicate with downstream computing. Ex. 1004, ¶¶ [0032], [0035], [0022], [0027]; Ex. 1002, ¶ 193. Specifically, the biomedical sensor 100 includes **a transmitter 108** that receives and transmits wirelessly signals received from the electrodes 104 through a signal processor 112. Ex. 1004, ¶¶ [0035], [0022], [0027]; Fig. 13; Ex. 1002, ¶ 193. Similarly, *Yang* discloses a

wireless sensor. Ex. 1005, 2:48-55; Ex. 1002, ¶ 193. Wireless communication of cardiac electrical signals existed in implantable devices well before 2013. Ex. 1002, ¶ 193.

A POSITA would understand that at least *Oster* discloses this element. Ex. 1002, ¶ 194.

### 2. Independent Claim 11

Claim 11 is an independent claim that differs from Claim 1 as shown in the comparison below.

| **Claim 1** | **Claim 11** |
|---|---|
| An electrocardiography patch, comprising:<br><br>a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing;<br><br>an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;<br><br>a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes; and<br><br>a wireless transceiver to communicate at least a portion of the electrocardiographic signals. | An electrocardiography monitor, comprising:<br><br>a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing;<br><br>an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;<br><br>a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes;<br><br>a wireless transceiver to communicate at least a portion of the electrocardiographic signals;<br><br>a battery on one of the ends of the |

| | |
|---|---|
| | backing;<br><br>a processor powered by the battery; and<br><br>memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals. |

As can be seen from the table, the only material difference between claims 1 and 11 is the additional recitation of the basic elements required to make a wireless patch function, namely the battery, the processor, and the memory, which are addressed and taught by the prior art shown below. Although the preamble slightly deviates between claims 1 and 11, a POSITA would understand that the electrocardiographic patch claimed by Claim 1 is an electrocardiographic monitor of Claim 11 and, thus, the different words in the preamble do not materially change the scope of preambles between Claims 1 and 11. Ex. 1002, ¶¶ 115-117, 195.

**a) Element [11-E]**

The combination of *Oster* and *Yang* discloses "a battery on one of the ends of the backing." *Oster* teaches that its wireless biomedical sensor system can create electromagnetic and electrical signals and provide an electrical conduit between its sensors and hubs. Ex. 1004, ¶¶ [0026], [0028], [0032], [0036]; Ex. 1002, ¶ 196. Such a wireless device would most obviously include a power source, such as a battery, to function. Ex. 1002, ¶ 196. Indeed, *Oster* discloses that its biomedical sensor system can be applied to telemetric and remote monitoring

devices, such as a Holter monitor. Ex. 1004, ¶ [0022]; Ex. 1002, ¶ 196. A POSITA would understand that a Holter monitor is a small, wearable battery-powered device for cardiac monitoring, which includes a replaceable battery. Ex. 1002, ¶ 196. Moreover, providing power to run the processor and sensors of the *Oster* patch is the most common way to power a device and as such it would *the* obvious way to do it. *Id*.

Nevertheless, a POSITA would understand that it is obvious to use a battery to power the wireless electronic monitoring systems such as *Oster*. Ex. 1002, ¶ 197. For example, *Yang* also teaches a wireless monitor and expressly discloses a battery 318 positioned directly on one end of the backing of the adherent patch (*e.g.*, the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306) to power the electrical component unit 312 of the flexible PCB 306 and the reusable module 106. Ex. 1005, 3:2-4, 63-4:2, 4:28-38, Fig. 3 (reproduced below); Ex. 1002, ¶ 197. And common sense dictates that the most obvious placement of the battery in *Oster* would be on one of is ends within one of its nodes, which provide the necessary space. Ex. 1002, ¶ 197.

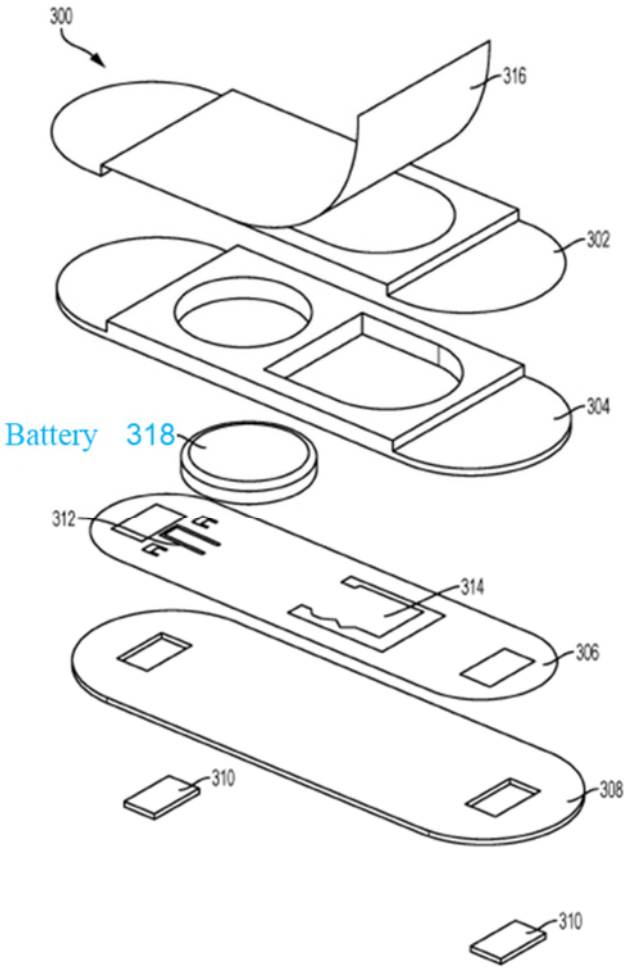



FIG. 3

Furthermore, just like the '743 patent, *Yang* teaches that its battery is housed on the replaceable portion of its patch (the disposable module 102 of *Yang* and/or the replaceable extended wear electrode patch of the '743 patent). Ex. 1002, ¶ 198. And similar to the '743 patent, *Yang* also teaches that its health monitoring device is cost-efficient because the reusable portion can be separated from the disposable portion (which houses the battery) and fitted with a new replacement disposable portion to extend its lifetime. Ex. 1005, 5:41-53; Ex. 1002, ¶ 198. A POSITA

would readily understand that *Yang's* teaching to reuse elements of the patch (such as the electronics) and replace other elements of the patch (such as the battery and the patch body), would improve the cost effectiveness of a disposable portion of a health monitoring device, such as that of *Oster*, which would include the consumable battery and create a product that is less wasteful. Ex. 1002, ¶ 198. Placing a battery as taught by *Yang* into one of the ends of the *Oster* patch would be a simple matter of packing well-understood components, which would be a routine and predictable for a POSITA. *Id*. Moreover, given the narrow and stretching design of the middle regions 106 of *Oster*, they would not be suitable for a battery or other bulky components. *Id*.

A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element and renders it obvious. Ex. 1002, ¶ 199.

**b) Element [11-F]**

The combination of *Oster* and *Yang* discloses "a processor powered by the battery." *Oster* teaches that the biomedical sensor system 100 can include a processor, such as a controller 114 or a signal processor 112. Ex. 1004, ¶¶ [0035], [0038]; Ex. 1002, ¶ 200. As with the battery element above, a POSITA would understand that the most obvious way to power the processor of an electrical device like *Oster's* would be with a battery. Ex. 1002, ¶ 200.

For example, a POSITA would also know that it is obvious to use a battery

to power the patch from prior art like *Yang*, which shows a battery 318 positioned directly on one end of the backing of the adherent patch (*e.g.*, the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306) to power the electrical component unit 312 of the flexible PCB 306 and the reusable module 106, which electrical component unit 312 includes a microcontroller (a processor). Ex. 1005, 3:2-4, 29-40, 63-4:2, 4:28-38; Ex. 1002, ¶ 201.

A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element and that it is obvious to power a wearable device—like the claimed patch—with a battery. Ex. 1002, ¶ 202.

**c) Element [11-G]**

*Oster* discloses "memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals." *Oster* teaches that the biomedical sensor system 100 can include a memory 116 to at least temporarily store information relative to the signals received from the satellite and/or hub electrodes 104. Ex. 1004, ¶ [0043]; *see also,* Ex. 1005 5:23-31 (explaining a POSITA would recognize the suitable addition of memory to the disclosed patch); Ex. 1002, ¶ 203. In fact, the storage of samples cardiac electrical signals has long been understood and practiced for decades. *Id*.

A POSITA would understand that at least *Oster* discloses this element and that it would be an obvious addition to an electrocardiograph monitor. Ex. 1002,

¶ 204.

**3. Claims 2 and 12**

Claim 2 depends on claim 1 and further requires that the ECG patch includes "an accelerometer provided on the backing." Similarly, Claim 12 depends on Claim 11 and further requires that there is "an accelerometer provided on the backing."

Activity sensors, including accelerometers, have long been understood and practiced for decades. Ex. 1002, ¶ 205. A POSITA would understand that *Oster* discloses this element and given the popularity of the quantified life movement by the priority date of the '743 it would be obvious to a POSITA to include an accelerometer in this sort of patch. *Id*. *Oster* expressly describes that in addition to sensing electrodes, its sensors can include an accelerometer. Ex. 1004, ¶ [0026]; Ex. 1002, ¶ 205.

A POSITA would understand that at least *Oster* discloses this element. Ex. 1002, ¶ 206.

**4. Claims 3 and 13**

Claim 3 depends on claim 1 and further requires that the ECG patch includes "a physiology sensor provided on the backing to measure body temperature." Claim 13 depends on claim 11 and further requires "a physiology sensor provided on the backing to measure body temperature."

Like the accelerometer of claims 2 and 12, *Oster* expressly describes that its sensors can include a thermocouple and/or sensors for sensing one or more of blood oxygen saturation, glucose, body temperature, blood pressure, and combinations thereof for creating one or more signals based on one or more physiological characteristics. Ex. 1004, ¶¶ [0024], [0026]; Ex. 1002, ¶ 208. Temperature sensors have long been understood and practiced for decades. Ex. 1002, ¶ 208 (citing Ex. 1008-1009).

A POSITA would understand that at least *Oster* discloses this element and, given the popularity of the quantified life movement by the priority date of the '743 patent, it would be obvious to a POSITA to include a temperature sensor in this sort of patch. Ex. 1002, ¶ 209.

**5. Claims 4 and 14**

Claim 4 depends on claim 1 and further requires that "each of the ends of the backing is rounded on an outer edge." Claim 14 depends on claim 11 and further requires "each of the ends of the backing [to be] rounded on an outer edge."

As shown in Fig. 2, the connector 106 (which includes the support members 164, 166 as the backing) terminates at the electrodes 104, which is shown to be rounded on an outer edge.

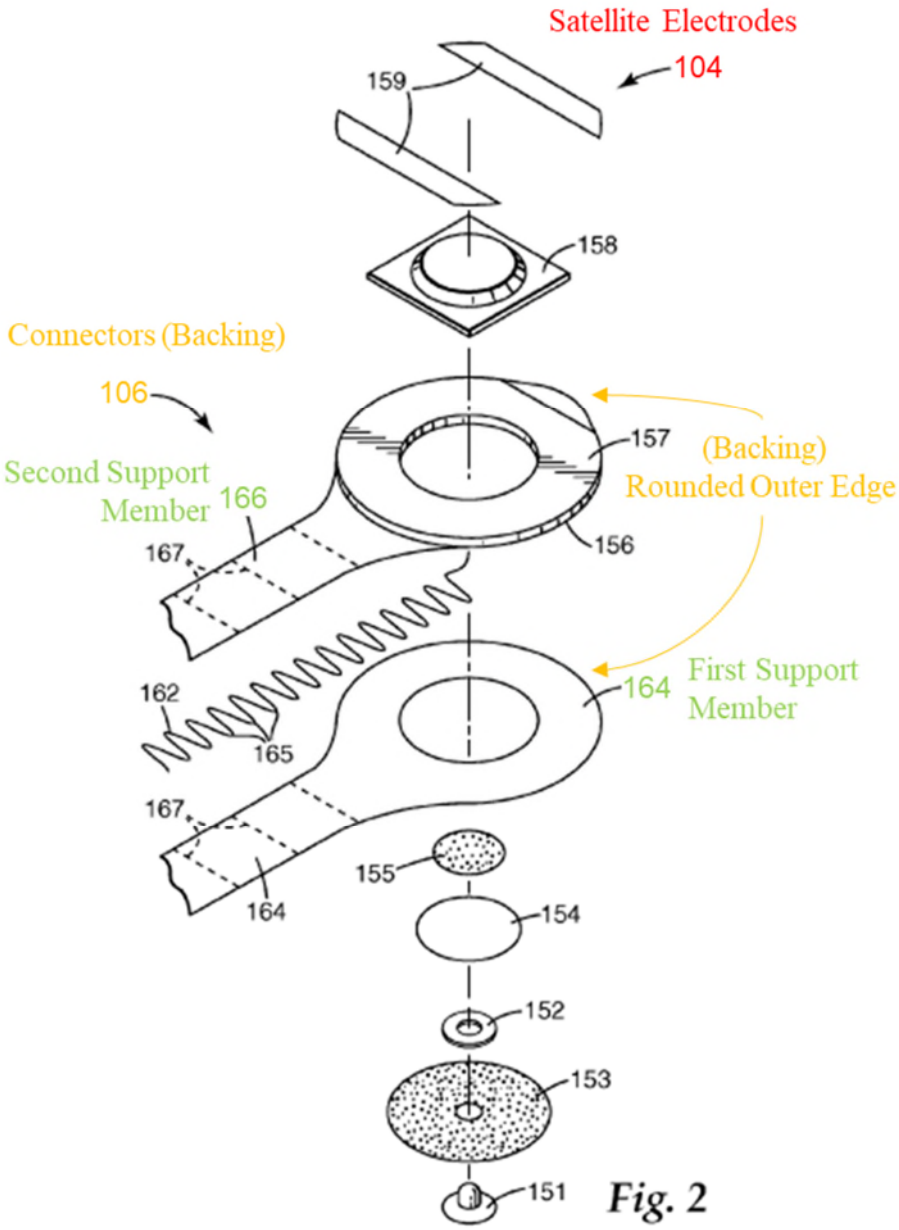



*Fig. 2*

A POSITA would understand that it would have been obvious to use rounded edges for comfort of the patient and for aesthetic reasons. Ex. 1002, ¶ 212. For example, the corners of squared off edges have a tendence to peel off since they come to a point. *Id*. Therefore, a POSITA would understand that at least *Oster* discloses this element. *Id*., *see also* the reasoning in Section VII.A.5

above.

### 6. Claims 5 and 15

Claim 5 depends on claim 1 and further requires "a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level." Claim 15 depends on claim 11 and further requires "a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned, and estimated blood glucose level."

Like claims 3 and 13, *Oster* states that its sensors include a thermocouple and/or sensors for sensing one or more of blood oxygen saturation, glucose, body temperature, blood pressure, and combinations thereof for creating one or more signals based on one or more physiological characteristics. Ex. 1004, ¶¶ [0021], [0024], [0026]; Ex. 1002, ¶ 214. Physiology and activity sensors measuring one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level have long been understood and practiced for decades. Ex. 1002, ¶ 214 (citing Ex. 1008-1012).

A POSITA would understand that at least *Oster* discloses this element and given the popularity of the quantified life movement by the priority date of the '743 patent, it would be obvious to a POSITA to include these sorts of sensors in

this sort of patch. Ex. 1002, ¶ 215.

**7. Claims 6 and 16**

Claim 6 depends on claim 1 and further requires that "the electrocardiographic signals are converted to a different format and processed." Claim 16 depends on claim 11 and further requires "the electrocardiographic signals [to be] converted to a different format and processed."

*Oster* teaches that the transmitter 108 is adapted to translate signals from the electrodes 104 into a signal that can be transmitted (*e.g.*, one or more of an electromagnetic signal, an acoustic signal, and combinations thereof), and wirelessly transmit information relative to the signal(s) from the electrodes 104 to a receiver 110. Ex. 1004, ¶¶ [0035], [0024], [0025], [0026]; Ex. 1002, ¶ 217. The conversion of electrocardiographic signals to a different format and processed has long been understood and practiced for decades. Ex. 1002, ¶ 217 (citing Ex. 1008, 1013).

A POSITA would understand that at least *Oster* discloses this element. Ex. 1002, ¶ 218.

**8. Claims 7 and 17**

Claim 7 depends on claim 6, which depends on claim 1, and further recites that "the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver." Claim 17

depends on claim 16, which depends on claim 11, and further requires that "the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver."

As described with reference to Claims 6 and 16, the transmitter 108 translates signals from the electrodes 104 and wirelessly transmits this information to a receiver 110. Ex. 1002, ¶ 220. *Oster* teaches that the receiver 110 can include or be a portion of a downstream computer, which comprises a client computer, as claimed. Ex. 1004, ¶¶ [0035], [0024], [0025], [0026]; Ex. 1002, ¶ 220. The retrieving of the formatted electrocardiographic signals has long been understood and practiced for decades. Ex. 1002, ¶ 220 (citing Ex. 1008).

Furthermore, by their nature, wireless patches send data to a computer for processing, otherwise the wireless transmission would be lost. Ex. 1002, ¶ 221. As such, this is an obvious feature that is commonly present in wireless patches. *Id*. A POSITA would understand that at least *Oster* discloses this element. *Id*.

**9. Claims 8 and 18**

Claim 8 depends on claim 1 and further recites that "the electrodes are exposed on a contact surface of the backing." Claim 18 depends on claim 11 and further requires that "the electrodes are exposed on a contact surface of the backing."

Fig. 2 shows an exploded view of the electrode 104, which shows that the

electrodes are on a contact surface of the backing of the connector 106. Ex. 1004, ¶¶ [0048], [0047], [0076]; Ex. 1002, ¶ 223. Additionally, *Oster* discloses an embodiment where the adhesive of the electrodes 104 can be directly coated onto a backing (*e.g.*, a support member 164, 166 of the connector 106) or it can be formed as a separate layer and laminated to the backing. *Id*. The effect of contact on tracing quality has been known for decades from an engineering and clinical perspective. Ex. 1002, ¶ 223. Skilled artisans understand the importance of electrode contact in the use of ECGs, for example, body hair is shaved/remove to ensure electrode contact. *Id*. Nevertheless, a POSITA would also understand that the electrodes are necessarily exposed to a contact surface of the surface it is attached to conduct electrical signals *Id*.

A POSITA would understand that *Oster* discloses this element. Ex. 1002, ¶ 224.

A POSITA would further understand that the placement of the electrodes/sensors on a contact surface of a backing was already well-known in the prior art and necessary for electronic components to function. Ex. 1002, ¶ 225. For example, *Yang* teaches a flexible PCB 306 coupled to at least two electrodes 310. Ex. 1005, 3:63-4:4, Fig. 3 (reproduced below); Ex. 1002, ¶ 225.

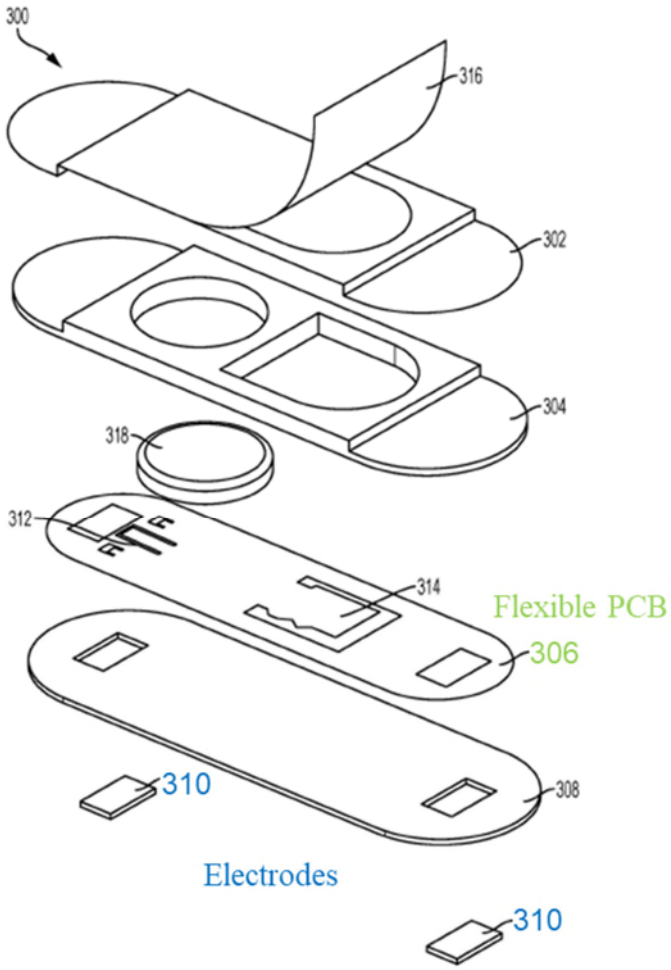



FIG. 3

*Yang* teaches that the flexible PCB 306 and bottom foam layer 308 each have two openings to allow for the coupling of the at least two electrodes 310 to the flexible PCB 306. Ex. 1005, 4:39-42; Ex. 1002, ¶ 226. A POSITA would readily understand that *Yang's* teaching of providing cutouts for its electrodes would necessarily include a placement of the electrodes on a contact surface of the backing (which includes the support members 164, 166 (not shown in Fig. 3) as the backing) to adhere to the patient. Ex. 1002, ¶ 226. Moreover, exposing the

electrodes on the bottom of the patch is the most obvious way to allow them to make contact with the patient and record the ECG signals. *Id*. Thus, this is the epitome of an obvious feature for this sort of device. *Id*. A POSITA would therefore be motivated to combine the teaching of *Oster* and *Yang* to include this in a wireless electrocardiograph patch. *Id*.

**10. Claims 9 and 19**

Claim 9 depends on claim 1 and further requires that the ECG patch includes "a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing." Claim 19 depends on claim 11 and further requires "a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing."

*Oster* discloses stretch release adhesives for at least a portion of a contact surface of the connector 106 to couple the electrodes 105 (and/or the hub 102) to the subject. Ex. 1004, Para. [0062]; Ex. 1002, ¶ 228. Additionally, *Oster* discloses that the electrodes 104 can include pregelled electrodes, wet gel electrodes, and combinations thereof. Ex. 1004, ¶ [0043]; Ex. 1002, ¶ 228. And *Oster* expressly teaches that these electrodes can include an adhesive, such as an adhesive hydrogel, a bicontinuous hydrogel pressure sensitive adhesive, and so on. *Id*. In fact, a POSITA would understand that in the context of applying adhesives to a subject's skin, it is obvious to use a non-irritating adhesive, such as a hydrocolloid adhesive. Ex. 1002, ¶ 228. As before, hydrocolloids were one of a few commonly

used adhesives for this sort of application. *Id*. A POSITA would understand that *Oster* discloses this element. *Id*. And that it is obvious to use hydrocolloid adhesives to attach electrode patches to a patient's skin. *Id*.

Additionally, a POSITA would understand that the placement of the hydrocolloid adhesive is a simple design choice that was already well-known in the prior art. Ex. 1002, ¶ 229. For example, the POSITA would understand that it is well known to apply the adhesives to specific parts of contact surface of the backing to ensure adhesion, such as taught by *Yang*. *Id*. For example, *Yang* shows a bottom foam layer 308 that includes a double adhesive layer positioned directly on one end of the backing of the adherent patch (*e.g.*, the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306) to adhere both to the flexible PCB 306 and to a user at the same time. Ex. 1005, 4:9-15, Fig. 3 (reproduced below); Ex. 1002, ¶ 230.

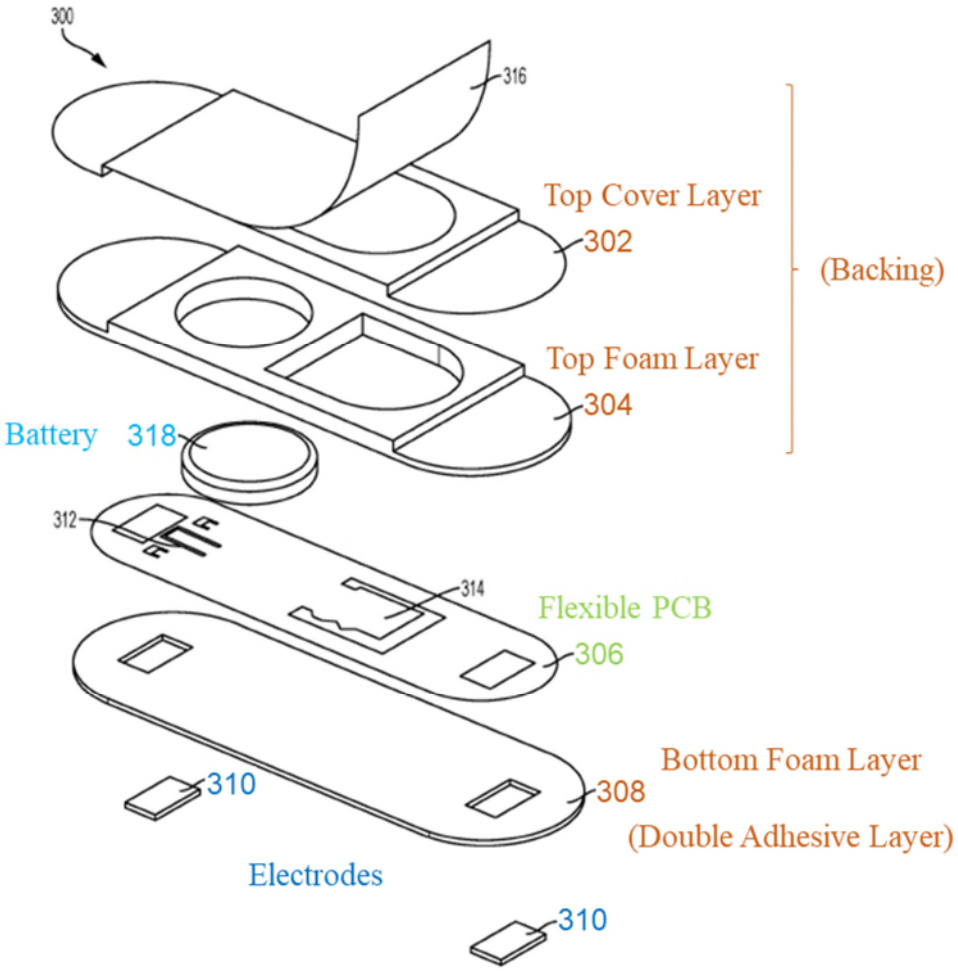



FIG. 3

A POSITA would understand that *Oster* and *Yang*, either alone or in combination, renders this element obvious. Ex. 1002, ¶ 231.

### 11. Claims 10 and 20

Claim 10 depends on claim 9, which depends on claim 1, and further recites that "the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface." Claim 20 depends on claim 19, which depends on claim 11, and further requires that "the hydrocolloid adhesive is provided on the ends of the

backing, on the contact surface."

Figs. 1 and 2 of *Oster* illustrate that the electrodes 104 and corresponding skin adhesives are provided on the ends of the backing, which is on the contact surface. Ex. 1002, ¶ 233. Furthermore, a POSITA would understand that in the context of applying adhesives to a subject's skin, it is obvious to use a non-irritating adhesive, such as a hydrocolloid adhesive, minimally as needed to secure the device. *Id*. In applying biomedical devices, the concept to also apply adhesives on the ends of the device has been well-known, for example, as illustrated by a Band-aid®. *Id.*

A POSITA would understand that at least *Oster* discloses this element. Ex. 1002, ¶ 234.

Nevertheless, a POSITA would readily understand that it is well known to apply the adhesives to specific parts of contact surface of the backing to ensure adhesion, such as taught by *Yang*. Ex. 1002, ¶ 235. This would include applying the adhesive to the border of the contact surface of the backing. *Id*.

Just like the '743 patent, *Yang* teaches that its "patch" looks like a "band-aid" and adheres to the user's body as such. Ex. 1005, 2:50-55; Ex. 1002, ¶ 236. A POSITA would readily understand that this principle of providing irritation free adhesives for biomedical use only on the ends of the backing, on a contact surface, as claimed, is expressly taught by the "band-aid" analogy taught by *Yang*. Ex.

1002, ¶ 236.

A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element. Ex. 1002, ¶ 237. And a POSITA would be motivated by the teachings of *Oster* and *Yang* to include this element in a wireless electrocardiographic patch. *Id*.

## VIII. SECONDARY CONSIDERATIONS

Petitioner is not aware of any secondary considerations that would overcome the strong showing of obviousness provided by the Petition. Further, any attempt by Bardy to rely on alleged secondary considerations cannot overcome the showing of obviousness detailed above. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1370 (Fed. Cir. 2011).

## IX. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that IPR of the '743 patent be instituted, and that Challenged Claims are cancelled.

Date: December 21, 2022

Respectfully submitted,

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**CERTIFICATE OF WORD COUNT**

The undersigned certifies that the foregoing PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,051,743 PURSUANT TO 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 complies with the type volume limitation in 37 C.F.R. § 42.24(a)(1). According to the utilized word-processing system's word count, the petition—excluding the caption, table of contents, table of exhibits, mandatory notices, certificate of word count, and certificate of service—contains 13,900 words.

Dated: December 21, 2022

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**CERTIFICATE OF SERVICE**

The undersigned hereby confirms that the foregoing PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,051,743 PURSUANT TO 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 and associated Exhibits 1001-1019 were caused to be served on December 21, 2022 via overnight courier upon the following counsel of record for Patent Owner:

CASCADIA INTELLECTUAL PROPERTY
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Copies of this Petition and associated Exhibits 1001-1019 were also served on December 21, 2022, via electronic mail, on Patent Owner's counsel of record in a related district court litigation:

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